

EXHIBIT C

Deposition Transcript of William J. Vigilante, Jr., Ph.D., CPE (08.18.16)

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1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF CONNECTICUT

3 RACHEL DENNERT,

4 Plaintiff,

5 -vs-

6 MEDTRONIC, INC.;

MEDTRONIC MINIMED,

7 INC., d/b/a MEDTRONIC

DIABETES, a Division of

8 MEDTRONIC, INC.

(improperly named as

9 MEDTRONIC DIABETES);

UNOMEDICAL DEVICES SA

10 de CV and UNOMEDICAL

A/S,

11 Defendants.
12

13 WILLIAMS CUKER BEREZOFSKY
14 1515 MARKET STREET - SUITE 1300
PHILADELPHIA, PENNSYLVANIA 19102

15 AUGUST 18, 2016

16 10:07 A.M.

17
18 VIDEOTAPED DEPOSITION OF
19 WILLIAM J. VIGILANTE, JR., Ph.D., CPE
20
21
22
23

24 REPORTED BY: DEBRA SAPIO LYONS, RDR, CRR, CRC, CCR, CPE

25 JOB NO: 111357

<p style="text-align: right;">Page 2</p> <p>1 2 3 4 5 August 18, 2016 6 Videotaped deposition of 7 William J. Vigilante, Jr., Ph.D., CPE, held at 8 the offices of Williams Cuker Berezofsky, 1515 9 Market Street, Suite 1300, Philadelphia, 10 Pennsylvania 19102, before Debra Sapio Lyons, a 11 Registered Diplomat Reporter, a Certified 12 Realtime Reporter, a Certified Realtime 13 Captioner, a Certified LiveNote Reporter, an 14 Approved Reporter of the United States District 15 Court for the Eastern District of Pennsylvania, a 16 Certified Court Reporter of the State of New 17 Jersey, a Notary Public of the States of New 18 Jersey, New York and the Commonwealth of 19 Pennsylvania. 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES: 2 WILLIAMS CUKER BEREZOFSKY 3 BY: KEVIN HAVERTY, ESQUIRE 4 SARAH HANSEL, ESQUIRE 5 210 Lake Drive East 6 Corporate Center 7 Cherry Hill, NJ 08002 8 Attorneys for Plaintiff Rachel Dennert 9 10 MASLON 11 BY: DAVID SCHULTZ, ESQUIRE 12 3300 Wells Fargo Center 13 90 South Seventh Street 14 Minneapolis, MN 55402 15 Attorneys for Defendant Medtronic, Inc.; 16 MEDTRONIC MINIMED, INC., d/b/a MEDTRONIC 17 DIABETES, a Division of MEDTRONIC, INC. 18 (improperly named as MEDTRONIC DIABETES) 19 20 THOMPSON HINE 21 BY: Z. ILEANA MARTINEZ, ESQUIRE 22 3560 Lenox Road Northeast 23 Atlanta, GA 30326 24 Attorneys for Defendant Unomedical 25 Devices SA de CV and Unomedical A/S ALSO PRESENT: GERARD ALFE, LEGAL VIDEO SPECIALIST TSG REPORTING</p>
<p style="text-align: right;">Page 4</p> <p>1 W. VIGILANTE 2 (The following is not recorded on 3 the videotaped record.) 4 MR. HAVERTY: Dave. 5 MR. SCHULTZ: Sure. Mr. Vigilante, 6 you've tendered to us a fee agreement that 7 you've asked my law firm and, I believe, 8 Ms. Martinez's law firm to execute; and 9 I've indicated to you that I do not intend 10 to execute it for the reason that I am 11 obligated under the rules, the Federal 12 Rules of Civil Procedure to pay you in 13 accordance with those rules, and I, of 14 course, will honor that obligation, but 15 what I won't do is sign a fee agreement for 16 an expert I have not retained which may or 17 may not purport to obligate I or my law 18 firm beyond the rules. So you've asked 19 that I execute it. I have indicated that I 20 will abide by the Rules Of Civil Procedure 21 and I will compensate you as required by 22 the rules, but I will not sign that fee 23 agreement. 24 MS. MARTINEZ: And I join 25 Medtronic's position on this issue.</p>	<p style="text-align: right;">Page 5</p> <p>1 W. VIGILANTE 2 MR. HAVERTY: And just so -- just so 3 we're clear, we want to put this on the 4 record so that we make sure that everybody 5 is covered in the event there's any type of 6 a dispute later on down the road. 7 MR. SCHULTZ: Fair enough. 8 THE VIDEOGRAPHER: Is everyone 9 ready? Okay. And could you put your mic 10 on? 11 (Discussion is held off the record.) 12 (The following is recorded on the 13 video record.) 14 THE VIDEOGRAPHER: This deposition 15 is now beginning. The date August 18th, 16 2016. The time 10:10. This is the 17 deposition of William J. Vigilante taken in 18 the matter of Rachel Dennert versus 19 Medtronic, Inc., et al. in the 20 United States District Court, District of 21 Connecticut, Civil Action Number 22 3-11-cv-01229(SRU). 23 Counsel will now introduce 24 themselves. 25 MR. HAVERTY: Good morning. Kevin</p>

<p style="text-align: right;">Page 6</p> <p>1 W. VIGILANTE</p> <p>2 Haverty, Williams Cuker Berezofsky for the</p> <p>3 Plaintiff.</p> <p>4 MS. HANSEL: Sarah Hansel, Williams</p> <p>5 Cuker Berezofsky also for the Plaintiff.</p> <p>6 MS. MARTINEZ: Ileana Martinez from</p> <p>7 Thompson Hine for the Unomedical</p> <p>8 Defendants.</p> <p>9 MR. SCHULTZ: Good morning. David</p> <p>10 Schultz, Maslon LLP on behalf of the</p> <p>11 Medtronic Defendants.</p> <p>12 - - -</p> <p>13 William J. Vigilante, Jr., PhD, CPE,</p> <p>14 having been first duly sworn, was examined</p> <p>15 and testified as follows:</p> <p>16 - - -</p> <p>17 EXAMINATION</p> <p>18 BY MR. SCHULTZ:</p> <p>19 Q. Good morning, Mr. Vigilante.</p> <p>20 A. Morning.</p> <p>21 Q. In your 13-year career as an</p> <p>22 expert witness, how many times have you been</p> <p>23 deposed?</p> <p>24 A. Somewhere over a hundred.</p> <p>25 Q. And in addition to that, how many</p>	<p style="text-align: right;">Page 7</p> <p>1 W. VIGILANTE</p> <p>2 times have you testified in a Court of Law?</p> <p>3 A. Maybe 36.</p> <p>4 Q. Okay. So the rules of this</p> <p>5 proceeding are well-known to you; correct?</p> <p>6 A. I think I have a general</p> <p>7 understanding.</p> <p>8 Q. Okay. You understand that I ask</p> <p>9 you questions, you got to provide me answers,</p> <p>10 correct, unless --</p> <p>11 A. Sure.</p> <p>12 Q. -- instructed to do otherwise;</p> <p>13 right?</p> <p>14 A. Sure.</p> <p>15 Q. Okay. And if you don't understand</p> <p>16 a question, you -- will you let me know that?</p> <p>17 A. I will do my best.</p> <p>18 Q. Okay. Well, if you don't indicate</p> <p>19 any misunderstanding or unclarity about the</p> <p>20 question, I'm going to assume that you've</p> <p>21 understood it.</p> <p>22 Is that a fair way to proceed?</p> <p>23 A. Sure.</p> <p>24 Q. All right. Is there any reason</p> <p>25 why today you are unable to give complete and</p>
<p style="text-align: right;">Page 8</p> <p>1 W. VIGILANTE</p> <p>2 accurate testimony?</p> <p>3 A. I don't believe so.</p> <p>4 Q. Who do you consider your client in</p> <p>5 this matter, Mr. Vigilante?</p> <p>6 A. Mr. Haverty.</p> <p>7 Q. How much have you earned in your</p> <p>8 13-year career as an expert witness?</p> <p>9 A. I have no idea.</p> <p>10 Q. Do you know how much you make a</p> <p>11 year?</p> <p>12 A. I knew what my salary was with my</p> <p>13 prior employer.</p> <p>14 Q. Okay. What was it?</p> <p>15 A. It's not for the record.</p> <p>16 Q. I'm sorry?</p> <p>17 A. It's not for the record.</p> <p>18 Q. Are you declining to answer that</p> <p>19 question?</p> <p>20 A. In the way it's asked, yes, I am.</p> <p>21 Q. Why?</p> <p>22 A. Because it's not for the record.</p> <p>23 It's --</p> <p>24 Q. What --</p> <p>25 A. -- it's a --</p>	<p style="text-align: right;">Page 9</p> <p>1 W. VIGILANTE</p> <p>2 Q. -- what do you mean "it's not for</p> <p>3 the record"?</p> <p>4 A. I'm not going to provide an answer</p> <p>5 to the question.</p> <p>6 Q. Well, Mr. Vigilante, I think</p> <p>7 you're required to do that, and I'd ask that</p> <p>8 you do that. If your counsel decides he wants</p> <p>9 to mark it confidential, he's free to do that.</p> <p>10 A. Yeah, my salary with my prior</p> <p>11 employer was confidential information. I'm</p> <p>12 not going to provide it on the record whether</p> <p>13 you mark it confidential or not. I can -- be</p> <p>14 happy to answer other questions related to how</p> <p>15 I'm compensated, but I'm not going to provide</p> <p>16 an answer to that question.</p> <p>17 MR. HAVERTY: Why don't we -- why</p> <p>18 don't we move on. We'll contact the Judge</p> <p>19 later about this. Is that all right,</p> <p>20 David?</p> <p>21 Q. Mr. Vigilante, how long have you</p> <p>22 been -- well, how long have you had Vigilante</p> <p>23 Forensics?</p> <p>24 A. I opened up for business on</p> <p>25 October 1st, 2015.</p>

<p style="text-align: right;">Page 10</p> <p>1 W. VIGILANTE</p> <p>2 Q. Since opening Vigilante Forensics</p> <p>3 up for business on October 15 -- or October</p> <p>4 1st of 2015, how much money have you earned as</p> <p>5 an expert witness?</p> <p>6 A. I don't know.</p> <p>7 Q. How much money -- you have no idea</p> <p>8 how much you've earned as an expert witness?</p> <p>9 A. My taxes haven't been done for the</p> <p>10 year. I don't know.</p> <p>11 Q. Well, I understand your taxes</p> <p>12 haven't been done, but you're just -- you're</p> <p>13 telling me that you just have no idea how much</p> <p>14 income you've brought home from your expert</p> <p>15 witness's services?</p> <p>16 A. Again, I can tell you that as of</p> <p>17 October 1st, 2015 all of my income that I</p> <p>18 generate is through my company, Vigilante</p> <p>19 Forensic.</p> <p>20 Q. Yeah, not my question. My</p> <p>21 question was how much money -- if you want me</p> <p>22 to rephrase it as Vigilante Forensics, how</p> <p>23 much money has Vigilante Forensics earned</p> <p>24 through your provision of expert witness</p> <p>25 services?</p>	<p style="text-align: right;">Page 11</p> <p>1 W. VIGILANTE</p> <p>2 A. Again, I -- I haven't done my</p> <p>3 taxes for the year, so I don't know or could</p> <p>4 give an answer for you other than that.</p> <p>5 Q. I'm not looking for a precise</p> <p>6 dollar amount. Are you able to give a</p> <p>7 reasonable approximation?</p> <p>8 A. My approximation is, is that all</p> <p>9 the money I've generated or the company has</p> <p>10 generated has been related to forensic work</p> <p>11 since I opened up for business on October 1st.</p> <p>12 Q. Right. And so the question is:</p> <p>13 In dollars what's your best estimate as to how</p> <p>14 much that is?</p> <p>15 A. It -- I don't know. I haven't</p> <p>16 done the taxes. I haven't been through to</p> <p>17 find out what the revenue is for the year.</p> <p>18 Q. Can you state what the gross</p> <p>19 income is of Vigilante Forensics?</p> <p>20 A. Again, I haven't calculated it.</p> <p>21 The best I can offer you is maybe the fourth</p> <p>22 quarter of 2015 was the last time that the</p> <p>23 taxes were done.</p> <p>24 Q. Yeah. So you pay estimated taxes;</p> <p>25 right?</p>
<p style="text-align: right;">Page 12</p> <p>1 W. VIGILANTE</p> <p>2 A. I do pay estimated taxes.</p> <p>3 Q. Okay. And you paid estimated</p> <p>4 taxes on fourth quarter of 2015; correct?</p> <p>5 A. No, I did not.</p> <p>6 Q. Okay. Did you pay estimated taxes</p> <p>7 on first quarter of 2016?</p> <p>8 A. Yes.</p> <p>9 Q. And estimated taxes on second</p> <p>10 quarter of 2016?</p> <p>11 A. Yes.</p> <p>12 Q. And the estimated taxes are based</p> <p>13 upon your best projection of the amount of</p> <p>14 revenues that Vigilante Forensics would</p> <p>15 generate; correct?</p> <p>16 A. It's based upon what my tax</p> <p>17 accountant does with the information that I</p> <p>18 provide him. He has access to my books. He</p> <p>19 looks through the money that's been collected.</p> <p>20 He looks at my tax liabilities. He looks at</p> <p>21 the other issues related to the taxes, and he</p> <p>22 tells me how much he's going to pull from the</p> <p>23 bank account.</p> <p>24 Q. And one piece of that information</p> <p>25 that your accountant looks at is how much</p>	<p style="text-align: right;">Page 13</p> <p>1 W. VIGILANTE</p> <p>2 revenue your company, Vigilante Forensics, is</p> <p>3 generating; correct?</p> <p>4 A. How much it's collected in, I</p> <p>5 would imagine, up to that point in time.</p> <p>6 Q. All right. And despite your --</p> <p>7 and you paid those taxes; right?</p> <p>8 A. Yes.</p> <p>9 Q. All right. And despite having</p> <p>10 paid those taxes, you're unable to give any</p> <p>11 reasonable approximation of how much revenue</p> <p>12 your company has generated through your</p> <p>13 services as an expert witness?</p> <p>14 A. I can tell you what my taxes were.</p> <p>15 I -- again, you're --</p> <p>16 Q. Okay.</p> <p>17 A. -- asking me to give you a guess,</p> <p>18 and it's my understanding as a rule for</p> <p>19 depositions is not to guess or speculate.</p> <p>20 So --</p> <p>21 Q. Actually --</p> <p>22 A. -- you're asking me to -- to guess</p> <p>23 at numbers I don't have and I don't have</p> <p>24 access to at the moment.</p> <p>25 Q. I'm actually not asking you to</p>

<p style="text-align: right;">Page 14</p> <p>1 W. VIGILANTE</p> <p>2 guess, and your counsel hasn't objected on</p> <p>3 that grounds, Mr. Vigilante. I've asked if</p> <p>4 you have a reasonable estimate, which is</p> <p>5 something different, and if you're saying you</p> <p>6 can't give me a reasonable estimate because it</p> <p>7 would be just a wild guess, I'll accept that</p> <p>8 testimony.</p> <p>9 A. Well, good. It would be a --</p> <p>10 Q. Is that what your testimony is?</p> <p>11 A. It -- I don't have a reasonable</p> <p>12 estimate to give to you at the moment.</p> <p>13 Q. Okay. Are you full time as an</p> <p>14 expert witness?</p> <p>15 A. I don't know what you mean by</p> <p>16 "full time." I run a -- a company that does</p> <p>17 forensic consulting.</p> <p>18 Q. Do you work 40 hours a week?</p> <p>19 How -- how much do you work?</p> <p>20 A. I wish I worked 40 hours a week.</p> <p>21 Sometimes it's 60. Sometimes it's 70.</p> <p>22 Q. Okay. And do you generate income</p> <p>23 through your company at the hourly rates that</p> <p>24 you have quoted to us in your fee agreement?</p> <p>25 A. Yeah, I have an hourly rate that I</p>	<p style="text-align: right;">Page 15</p> <p>1 W. VIGILANTE</p> <p>2 have a agreement for with clients, and they</p> <p>3 pay the hourly late -- hopefully they pay the</p> <p>4 hourly rate when I invoice them.</p> <p>5 Q. And the hourly rate --</p> <p>6 A. Sometimes I have problems</p> <p>7 collecting. Sometimes I have clients that</p> <p>8 aren't -- that want to negotiate the final</p> <p>9 invoice. It just -- it's -- it's variable.</p> <p>10 Q. Your hourly rate is what?</p> <p>11 A. Currently it's \$350.00 an hour for</p> <p>12 all case-related work except for videotaped</p> <p>13 testimony which is 435 an hour.</p> <p>14 Q. Now, why do you charge more for</p> <p>15 videotaped testimony?</p> <p>16 A. Because it's a more stressful</p> <p>17 event. It's harder to -- to testify under</p> <p>18 video and it takes more effort during the</p> <p>19 deposition or the trial testimony or what have</p> <p>20 you.</p> <p>21 Q. Okay. So you find -- you -- are</p> <p>22 you saying that you find this videotaped</p> <p>23 deposition to be stressful?</p> <p>24 A. Yeah. I wasn't trained as an</p> <p>25 anchor or newscaster. I'm not used to sitting</p>
<p style="text-align: right;">Page 16</p> <p>1 W. VIGILANTE</p> <p>2 in front of a camera having to talk to a</p> <p>3 camera for hours at end. So it's a unusual</p> <p>4 and more stressful situation than a regular</p> <p>5 deposition or trial testimony that's not</p> <p>6 videotaped.</p> <p>7 Q. Would it be less stressful if you</p> <p>8 looked me in the eye instead of looking solely</p> <p>9 at the camera?</p> <p>10 A. I think that I'm supposed to be</p> <p>11 looking at the camera because I'm being</p> <p>12 videotaped. Why would I be looking at you if</p> <p>13 I'm going to be videotaping to the camera --</p> <p>14 Q. That's your understanding --</p> <p>15 A. -- or being videotaped by the</p> <p>16 camera.</p> <p>17 Q. That's your understanding of what</p> <p>18 a rule is in this deposition for your conduct?</p> <p>19 A. I don't think there is any rules</p> <p>20 for videotaped testimony, but, again, you're</p> <p>21 videotaping me. I'm going to be looking at</p> <p>22 the camera.</p> <p>23 Q. Okay. Well, if there's anything</p> <p>24 that causes you to want to look me in the eye,</p> <p>25 feel free to do that, okay, so that you're not</p>	<p style="text-align: right;">Page 17</p> <p>1 W. VIGILANTE</p> <p>2 feeling as if you have to look at the camera</p> <p>3 at all times, Mr. Vigilante.</p> <p>4 Why don't you tell me about your</p> <p>5 educational background if you would.</p> <p>6 A. What would you like to know?</p> <p>7 Q. Well, let's do it this way.</p> <p>8 MR. HAVERTY: Can we just go off the</p> <p>9 record real quickly?</p> <p>10 THE VIDEOGRAPHER: One moment. We</p> <p>11 are now going off the video record. The</p> <p>12 time, 10:20.</p> <p>13 (A recess is held from 10:20 a.m. to</p> <p>14 10:22 a.m.)</p> <p>15 (Exhibit Vigilante-1, multipage</p> <p>16 document entitled William J. Vigilante Jr.,</p> <p>17 PhD, CPE, Human Factors/Ergonomics Expert,</p> <p>18 is marked for identification.)</p> <p>19 THE VIDEOGRAPHER: Back on, 10:22.</p> <p>20 MR. SCHULTZ: Go ahead and hand that</p> <p>21 to the witness.</p> <p>22 THE WITNESS: Thank you.</p> <p>23 BY MR. SCHULTZ:</p> <p>24 Q. Mr. Vigilante, the court reporter</p> <p>25 has handed you what's been marked as Exhibit 1</p>

<p style="text-align: right;">Page 18</p> <p>1 W. VIGILANTE</p> <p>2 which is a copy of the CV you have provided in</p> <p>3 conjunction with this case.</p> <p>4 Do you recognize that document as</p> <p>5 I've described it?</p> <p>6 A. Yes.</p> <p>7 Q. And is that a complete statement</p> <p>8 of your credentials and qualifications as you</p> <p>9 understand them?</p> <p>10 A. It is. There's been an update to</p> <p>11 it. So that would be the only caveat.</p> <p>12 Q. What's the update?</p> <p>13 A. There's a newer version of it.</p> <p>14 Q. Okay. What's the difference</p> <p>15 between the new version and the version that</p> <p>16 was provided? Just more testimony or --</p> <p>17 A. I believe the -- the difference is</p> <p>18 some edits I made in the grammar and some</p> <p>19 spelling errors --</p> <p>20 Q. Okay.</p> <p>21 A. -- but I -- my current CV has a</p> <p>22 different date on it. That's how I know that</p> <p>23 it's different.</p> <p>24 Q. Okay. But in terms of relating</p> <p>25 the training and experience that you rely upon</p>	<p style="text-align: right;">Page 19</p> <p>1 W. VIGILANTE</p> <p>2 in this case for your opinions, that version</p> <p>3 of the CV accurately and completely conveys</p> <p>4 that training and experience; correct?</p> <p>5 A. Yeah, I'd say it was adequate for</p> <p>6 that reason.</p> <p>7 Q. Okay.</p> <p>8 A. The --</p> <p>9 Q. Is there any --</p> <p>10 A. Just the -- my updated CV has a</p> <p>11 date of July 2016 --</p> <p>12 Q. Okay.</p> <p>13 A. -- and I can -- happy to provide</p> <p>14 you with a copy of that.</p> <p>15 Q. Have you received any additional</p> <p>16 degrees or certifications since that are</p> <p>17 reflected in your updated CV?</p> <p>18 A. No.</p> <p>19 Q. All right. And is there any</p> <p>20 experience or training that you are relying on</p> <p>21 in rendering your opinions in this case that</p> <p>22 isn't reflected on the CV that's been marked</p> <p>23 as Exhibit 1?</p> <p>24 A. No.</p> <p>25 Q. And I take it there is nothing</p>
<p style="text-align: right;">Page 20</p> <p>1 W. VIGILANTE</p> <p>2 that you would describe as inaccurate or</p> <p>3 misleading on your CV; correct?</p> <p>4 A. There's nothing misleading. There</p> <p>5 was some inaccuracies, that's why I had to go</p> <p>6 and edit it, but nothing misleading.</p> <p>7 Q. Okay. Your CV says that you have</p> <p>8 a Ph.D. -- among other things, it says you</p> <p>9 have a Ph.D. in psychology/ergonomics. Does</p> <p>10 your -- did you actually receive a degree in</p> <p>11 ergonomics or are you simply conveying that</p> <p>12 that was your area within psychology that you</p> <p>13 studied?</p> <p>14 A. Yeah, technically it's a Doctorate</p> <p>15 of Philosophy, but my department that the</p> <p>16 degree was earned in was in the Psychology</p> <p>17 Department, and the area in which I studied in</p> <p>18 that department was the ergonomics area.</p> <p>19 Q. Okay. And I guess what I'm asking</p> <p>20 is: The institution from which you got your</p> <p>21 degree does not say you have a doctorate in</p> <p>22 ergonomics; correct? That's not the way they</p> <p>23 describe it.</p> <p>24 A. I don't know. I can tell you that</p> <p>25 the diploma says doctor of -- Doctorate of</p>	<p style="text-align: right;">Page 21</p> <p>1 W. VIGILANTE</p> <p>2 Philosophy. I don't know how NC State</p> <p>3 would -- would present it.</p> <p>4 Q. Okay. Well, and your doctorate</p> <p>5 was earned through the Psychology Department;</p> <p>6 correct?</p> <p>7 A. Yes, I was a student in the</p> <p>8 Psychology Department.</p> <p>9 Q. Okay. And is there a Department</p> <p>10 of Ergonomics at North Carolina State</p> <p>11 University?</p> <p>12 A. No.</p> <p>13 Q. All right. What is ergonomics?</p> <p>14 A. Ergonomics or human factors are</p> <p>15 synonyms, is basically the science that</p> <p>16 studies how people interact with or use all</p> <p>17 different types of products, machines, and</p> <p>18 systems; and what we focus on are the people</p> <p>19 that are going to be using the systems, the</p> <p>20 products, and so forth. We're interested in</p> <p>21 how people capture information through their</p> <p>22 senses, through their ear -- their hearing,</p> <p>23 their -- their visual senses and so forth, how</p> <p>24 they make sense of that information, how they</p> <p>25 make decisions, how they learn, how they're</p>

<p style="text-align: right;">Page 22</p> <p>1 W. VIGILANTE</p> <p>2 able to -- how memory is affected by the</p> <p>3 information they get and how memory affects</p> <p>4 the information -- how they interpret the</p> <p>5 information they collect. We look at also</p> <p>6 things such as physical strength,</p> <p>7 coordination, and so forth.</p> <p>8 The goal of human factors is to</p> <p>9 take the information we learn about the user</p> <p>10 and apply it to the design of products,</p> <p>11 machines, and systems so that products are</p> <p>12 easy to use, they're comfortable for the users</p> <p>13 that have to use them, and that they're safe</p> <p>14 for use by the multiple users that are likely</p> <p>15 to use them.</p> <p>16 Q. Is it your view that ergonomics</p> <p>17 and human factors -- did you say they're</p> <p>18 synonymous?</p> <p>19 A. Yes.</p> <p>20 Q. All right. You said earlier that</p> <p>21 you formed Vigilante Forensics on October 1st</p> <p>22 of 2015; correct?</p> <p>23 A. That's the day I started business.</p> <p>24 Q. Okay. When did you form it?</p> <p>25 A. The LLC is technically</p>	<p style="text-align: right;">Page 23</p> <p>1 W. VIGILANTE</p> <p>2 Vigilante Consulting, and it was sometime</p> <p>3 prior to October 1st.</p> <p>4 Q. And why did you decide to form</p> <p>5 Vigilante Forensics or Vigilante Consulting?</p> <p>6 A. Yeah, I wanted to do -- I wanted</p> <p>7 to have my own company, so I was, I guess,</p> <p>8 advised to open an LLC. So I opened an LLC to</p> <p>9 do business as Vigilante Consulting.</p> <p>10 I offer both forensic consulting</p> <p>11 and traditional consulting, so I didn't want</p> <p>12 to call the LLC Vigilante Forensic. So I</p> <p>13 applied for a doing business as Vigilante</p> <p>14 Forensic so that I can still do traditional</p> <p>15 consulting work under</p> <p>16 Vigilante Consulting, LLC. I know it's a</p> <p>17 little confusing, but that's kind of the</p> <p>18 reason for it.</p> <p>19 Q. Are there two separate</p> <p>20 organizations?</p> <p>21 A. No.</p> <p>22 Q. Okay. Do you do what you call</p> <p>23 "traditional consulting" under Vigilante</p> <p>24 Forensic?</p> <p>25 A. No, I would send the -- if a</p>
<p style="text-align: right;">Page 24</p> <p>1 W. VIGILANTE</p> <p>2 client calls and wants me to do traditional</p> <p>3 consulting work, I would send them a -- an</p> <p>4 agreement, much like the agreement I sent to</p> <p>5 Mr. Haverty for my involvement in his case,</p> <p>6 and it would be titled under</p> <p>7 Vigilante Consulting, LLC.</p> <p>8 Q. Okay. And when you're engaged in</p> <p>9 litigation or legal-related work, you issue</p> <p>10 your invoices and your agreements under the</p> <p>11 name "Vigilante Forensic"; correct?</p> <p>12 A. Actually, the invoices are sent</p> <p>13 under Vigilante Consulting, LLC doing business</p> <p>14 as Vigilante Forensic.</p> <p>15 Q. Okay. So there's not two separate</p> <p>16 LLCs?</p> <p>17 A. No, there's only one LLC.</p> <p>18 Q. All right. Do you -- when you</p> <p>19 say -- well, let me ask it this way. Since</p> <p>20 forming Vigilante Consulting, LLC, have you</p> <p>21 done any traditional consulting?</p> <p>22 A. I've had a few proposals out, but</p> <p>23 I haven't generated any income through</p> <p>24 Vigilante Consulting, LLC doing traditional</p> <p>25 consulting work.</p>	<p style="text-align: right;">Page 25</p> <p>1 W. VIGILANTE</p> <p>2 Q. Have you -- and I take it you are</p> <p>3 not under any current engagements to do any</p> <p>4 traditional consulting?</p> <p>5 A. Correct.</p> <p>6 Q. What do you mean by "traditional</p> <p>7 consulting"?</p> <p>8 A. Non-litigation related. So a</p> <p>9 manufacturer may come to me and ask me to help</p> <p>10 them with their product design, usability</p> <p>11 testing, warning assessment, things of that</p> <p>12 nature.</p> <p>13 Q. So to date, which is about ten</p> <p>14 months operating Vigilante Consulting dba</p> <p>15 Vigilante Forensic, all of your engagements</p> <p>16 have been forensic work; correct?</p> <p>17 A. All revenue I've generated since</p> <p>18 opening the company has been forensic or</p> <p>19 litigation related.</p> <p>20 Q. Okay. Why the qualification?</p> <p>21 A. 'Cause I really didn't understand</p> <p>22 your question fully and I wanted to make sure</p> <p>23 I was clear.</p> <p>24 Q. Okay. Have you done other work</p> <p>25 under Vigilante Consulting that hasn't</p>

<p style="text-align: right;">Page 26</p> <p>1 W. VIGILANTE 2 generated revenues? 3 A. Like I said, I submitted a few 4 proposals for traditional consulting work -- 5 Q. Okay. 6 A. -- for clients that were 7 interested. 8 Q. All right. But that's it; right? 9 In other words, you're not 10 providing some services for which you're not 11 getting revenues under Vigilante Consulting? 12 A. No. Like I said, the -- the only 13 thing I've done other -- that's not litigation 14 related is I have submitted a few proposals on 15 the request of clients that were 16 non-litigation related, were non-lawyers that 17 were looking for work to be done. So I spoke 18 with them, generated the proposal, sent them 19 off, and that's where they stand. 20 Q. Have you heard that any of those 21 proposals have expired, meaning that it's not 22 that they're open, but a decision has been 23 made and they've gone in a different 24 direction? 25 A. I have not heard either way.</p>	<p style="text-align: right;">Page 27</p> <p>1 W. VIGILANTE 2 Q. Okay. Have any of those proposals 3 been made to medical device manufacturers? 4 A. No. 5 Q. Pharmaceutical companies? 6 A. No. 7 Q. In terms of the nomenclature, when 8 you say "forensic work," you're using 9 "forensic" in the sense of legal related; 10 correct? 11 A. Well, typically it's legal 12 created -- or typically it's legal related for 13 the work that I do, but technically forensic 14 is just the investigation of an incident to 15 determine root cause and other variables that 16 may have been involved. 17 Q. Okay. Well, I just want to make 18 sure I understand how you're using the word 19 "forensic" in your dba. So is that what 20 you're intending to communicate, that you're 21 engaged in forensic work? 22 A. Yeah, I chose the name to have a 23 connotation that I do forensic-related work. 24 Q. Okay. And by that you mean what? 25 A. I don't understand. That I do</p>
<p style="text-align: right;">Page 28</p> <p>1 W. VIGILANTE 2 forensic-related work. 3 Q. What do you mean by 4 "forensic-related work"? 5 MR. HAVERTY: He just -- he just 6 said what. 7 A. Yeah, so technically it's for 8 anything that involves incident investigation 9 to determine root causes and -- and the roles 10 and responsibility of the people involved and 11 what could have been done to prevent it. Most 12 of my work is done in the litigation arena. 13 Q. Well, since forming 14 Vigilante Consulting dba Vigilante Forensic, 15 have you done any forensic work that was not 16 litigation related? 17 A. I don't believe so. 18 Q. How many employees does Vigilante 19 Consulting have? 20 A. I don't have any employees. 21 Q. Okay. So the company -- you and 22 the company are synonymous in terms of -- 23 well, strike that. That's a bad question. 24 You're the owner of the company; 25 right?</p>	<p style="text-align: right;">Page 29</p> <p>1 W. VIGILANTE 2 A. Yes. 3 Q. And you have no employees other 4 than yourself if you call yourself an 5 employee? 6 A. Yeah, I don't have any other 7 employees. 8 Q. Okay. Where is your office? 9 A. I work out of my home office. 10 Q. And where is that? 11 A. Do you want the street address or 12 do you want the location? 13 Q. Street address would be good. 14 Thanks. 15 A. 200 Pembroke Circle, 16 Phoenixville, PA 19460. 17 Q. Okay. And do you have any 18 certifications? 19 A. Yes. 20 Q. What do -- what certifications do 21 you hold? 22 A. I'm board certified by the -- I'm 23 a board certified professional ergonomist. 24 Q. Okay. What's the certification 25 procedure for that organization?</p>

<p style="text-align: right;">Page 30</p> <p>1 W. VIGILANTE</p> <p>2 A. There is a application that you</p> <p>3 have to complete. You have to have, I think,</p> <p>4 some prerequisites related to the amount of</p> <p>5 years that you've been doing work in the field</p> <p>6 of ergonomics/human factors. Once you submit</p> <p>7 the application, if you have the</p> <p>8 prerequisites, they request you to submit a</p> <p>9 portfolio of work that you've done over the</p> <p>10 years. The portfolio of work is apparently</p> <p>11 given to a panel of reviewers for</p> <p>12 determination of whether or not it's adequate,</p> <p>13 appropriate, et cetera, meets the standards of</p> <p>14 the Certification Board.</p> <p>15 If they're happy with that, you</p> <p>16 have to sit for an exam. The exam covers the</p> <p>17 different areas of human factors ergonomic --</p> <p>18 ergonomics. You have to have a certain score</p> <p>19 on the exam, a passing score on the exam. If</p> <p>20 you pass the exam, they give you a board</p> <p>21 certification; and then to keep the</p> <p>22 certification, you have to meet certain</p> <p>23 continuing education requirements.</p> <p>24 Q. Anything else you have to do in</p> <p>25 order to maintain certification other than</p>	<p style="text-align: right;">Page 31</p> <p>1 W. VIGILANTE</p> <p>2 continuing education?</p> <p>3 A. Technically you have to -- I guess</p> <p>4 there's like a form. I haven't gotten there</p> <p>5 yet. I think it's every three years you have</p> <p>6 to submit a form to the Certification Board</p> <p>7 with the list of the continuing education and</p> <p>8 then the proof that you attended the</p> <p>9 continuing education. And there are so many</p> <p>10 points of different types of education, and as</p> <p>11 long as the points meet their criteria,</p> <p>12 they'll continue to allow you to be listed on</p> <p>13 their registry. I assume that if you don't</p> <p>14 meet their requirements, there may be some</p> <p>15 time period in which to meet them. I -- I</p> <p>16 don't know yet.</p> <p>17 Q. All right. When -- when did you</p> <p>18 become first certified?</p> <p>19 A. I believe it's been either the</p> <p>20 spring of '15 or the spring of '14, but within</p> <p>21 the last two years.</p> <p>22 Q. And when you say you had to submit</p> <p>23 some information about your work, can you give</p> <p>24 me an idea of what -- what was the nature of</p> <p>25 the information you submitted?</p>
<p style="text-align: right;">Page 32</p> <p>1 W. VIGILANTE</p> <p>2 A. I think I submitted some of the</p> <p>3 peer-reviewed scientific research that I've</p> <p>4 conducted. I believe I submitted a report</p> <p>5 that I had done for a -- a litigation-related</p> <p>6 case. I don't know -- I don't remember what</p> <p>7 else I did.</p> <p>8 Q. Have you held any other</p> <p>9 certifications in your professional areas of</p> <p>10 endeavor?</p> <p>11 A. Yes, so the -- I think the -- the</p> <p>12 answer is yes -- or, excuse me, the answer is,</p> <p>13 no, I don't hold any other certifications</p> <p>14 related to my field. I do hold some other</p> <p>15 certifications that are related to the type of</p> <p>16 work that I get involved with, but I wouldn't</p> <p>17 call them -- they're professional</p> <p>18 organizations, but I wouldn't call them like a</p> <p>19 academic professional organization like human</p> <p>20 factors or ergonomics or that thing.</p> <p>21 Q. What other certifications do you</p> <p>22 hold?</p> <p>23 A. Like, for example, I have -- I'm</p> <p>24 certified for -- I'm a certified forklift</p> <p>25 operator. I'm -- I've received certification</p>	<p style="text-align: right;">Page 33</p> <p>1 W. VIGILANTE</p> <p>2 from the Motorcycle Safety Foundation through</p> <p>3 different courses, the NRA through different</p> <p>4 courses as an instructor. I think there's</p> <p>5 a -- maybe a few more of them that are listed.</p> <p>6 In the past I've had like Fall Protection</p> <p>7 Certification, Confined Space Certification.</p> <p>8 So kind of things of that nature.</p> <p>9 Q. Who issues these certifications</p> <p>10 you're referring to now?</p> <p>11 A. There's multiple different</p> <p>12 parties.</p> <p>13 So, for example, the motorcycle</p> <p>14 stuff is -- is done through the Motorcycle</p> <p>15 Safety Foundation.</p> <p>16 Raymond offered the certification</p> <p>17 for -- for forklift operation.</p> <p>18 The confined space and the fall</p> <p>19 protection were done by a -- they were done</p> <p>20 through -- through OSHA, but they were not</p> <p>21 done by OSHA. It was a -- it was a -- kind of</p> <p>22 an OSHA consultant that came in and gave the</p> <p>23 training that issued the certification based</p> <p>24 on OSHA's requirements.</p> <p>25 Q. And the NRA you referenced</p>

<p style="text-align: right;">Page 34</p> <p>1 W. VIGILANTE</p> <p>2 earlier, that's the National Rifle</p> <p>3 Association?</p> <p>4 A. Yes.</p> <p>5 Q. Have you ever had a certification</p> <p>6 withdrawn or disciplined in any way?</p> <p>7 A. No.</p> <p>8 Q. The certifying board --</p> <p>9 A. Oh, I take that back. I think my</p> <p>10 Confined Space Certification has lapsed and</p> <p>11 it's possible my Fall Protection Certification</p> <p>12 has lapsed. They require training every so</p> <p>13 many years. Like you have to sit through a</p> <p>14 class every so many years, so I think they may</p> <p>15 have lapsed over time.</p> <p>16 Q. You -- and I assume you let them</p> <p>17 lapse; right, you didn't seek recertification?</p> <p>18 A. I did not seek recertification.</p> <p>19 Q. All right. What's Confined Space</p> <p>20 Certification? What does that deal with?</p> <p>21 A. Technically from a workplace</p> <p>22 safety standpoint, OSHA standpoint, you can't</p> <p>23 have people go into confined spaces without</p> <p>24 being certified to -- to go into them because</p> <p>25 of the potential danger associated with</p>	<p style="text-align: right;">Page 35</p> <p>1 W. VIGILANTE</p> <p>2 confined spaces and essentially asphyx --</p> <p>3 asphyxiating [sic] due to lack of oxygen or</p> <p>4 other gases that may be present.</p> <p>5 Q. And the Fall Protection</p> <p>6 Certification, what is that?</p> <p>7 A. That's -- again, it's a</p> <p>8 certification offered by OSHA for ensuring</p> <p>9 that you are -- are familiar with and know the</p> <p>10 requirements and -- the safety requirements</p> <p>11 for working at height. So I think -- I don't</p> <p>12 remember how -- what the minimum height is,</p> <p>13 but if you're going to be up 20, 30, 40 feet</p> <p>14 working, you need to be tied in at all times</p> <p>15 and there's different ways to do it. There's</p> <p>16 different equipment to do it. So the</p> <p>17 certification ensures you have the training to</p> <p>18 know what the requirements are and what that</p> <p>19 equipment is and how the equipment's used.</p> <p>20 Q. All right. So is it a fair</p> <p>21 summary to say that certifications like fall</p> <p>22 protection and confined spaces, those that are</p> <p>23 not the Board of Professional Ergonomics,</p> <p>24 those are essentially testing to see whether</p> <p>25 you're familiar with the various applicable</p>
<p style="text-align: right;">Page 36</p> <p>1 W. VIGILANTE</p> <p>2 regulations such as OSHA?</p> <p>3 A. The way I would phrase it is that</p> <p>4 it's all part of a training package, and at</p> <p>5 the end of the training you're provided the</p> <p>6 certification. The certification lets the</p> <p>7 people know that need to know that you've been</p> <p>8 through the training, you've had the training</p> <p>9 and that you've exercise -- or are able to</p> <p>10 demonstrate the knowledge from that training</p> <p>11 so that they know that you're -- you're</p> <p>12 trained and appropriate for whatever the task</p> <p>13 may be.</p> <p>14 Q. Over the last 13 year -- well,</p> <p>15 prior to being at Vigilante Consulting dba</p> <p>16 Vigilante Forensics, you were with ROBE-SON</p> <p>17 Forensics or ROB-SON? How is it pronounced?</p> <p>18 A. ROB-SON.</p> <p>19 Q. Okay. And in that role you also</p> <p>20 did litigation-related work; correct?</p> <p>21 A. Yes.</p> <p>22 Q. Over -- and you were there for how</p> <p>23 long?</p> <p>24 A. Since July of 2003, so a little</p> <p>25 over 12 years.</p>	<p style="text-align: right;">Page 37</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay. During that -- so then</p> <p>3 looking back from 2003 to the present, you've</p> <p>4 been involved in litigation-related</p> <p>5 consulting; correct?</p> <p>6 A. Sure.</p> <p>7 Q. What percentage of your time was</p> <p>8 litigation-related consulting or expert work</p> <p>9 as opposed to what you've called "traditional</p> <p>10 consulting"?</p> <p>11 A. When I was with Robson Forensic,</p> <p>12 my billable hours percentage wise for</p> <p>13 litigation versus non-litigation was probably</p> <p>14 on the order of 90, 95 percent litigation, 5,</p> <p>15 10 percent traditional consulting.</p> <p>16 Q. All right. And so far, as we've</p> <p>17 established under Vigilante Consulting, in</p> <p>18 terms of revenue-generating activities, it's</p> <p>19 been a hundred percent litigation?</p> <p>20 A. Yes.</p> <p>21 Q. Have you -- and within that</p> <p>22 litigation experience, what percentage has</p> <p>23 been on behalf of plaintiffs seeking damages</p> <p>24 against a defendant as opposed to a defendant</p> <p>25 in a case?</p>

<p style="text-align: right;">Page 38</p> <p>1 W. VIGILANTE</p> <p>2 A. For civil litigation it's probably</p> <p>3 about 60/40 over -- over time.</p> <p>4 Q. And, you know, you've mentioned</p> <p>5 that do you some -- or have done some</p> <p>6 criminal-related work; is that correct?</p> <p>7 A. I -- I have done -- I have been a</p> <p>8 consultant in criminal-related work.</p> <p>9 Q. How many times?</p> <p>10 A. I don't -- I don't know. I can't</p> <p>11 give you a number.</p> <p>12 Q. Do you think it's more than ten?</p> <p>13 A. I would say more than ten.</p> <p>14 Q. And in those circumstances, are</p> <p>15 you typically engaged on behalf of the</p> <p>16 criminal defendant or the prosecutor's office?</p> <p>17 A. I would think the majority of</p> <p>18 criminal cases I've been hired on behalf of</p> <p>19 the defendant. The majority of the time.</p> <p>20 Q. Okay. Have you ever been hired by</p> <p>21 the prosecuting office?</p> <p>22 A. I believe so.</p> <p>23 Q. How many times?</p> <p>24 A. I don't recall.</p> <p>25 Q. Is that something that you keep</p>	<p style="text-align: right;">Page 39</p> <p>1 W. VIGILANTE</p> <p>2 track of? Is that information available to</p> <p>3 you in some form?</p> <p>4 A. I don't keep track of it.</p> <p>5 Q. Have you -- in your civil</p> <p>6 experience, have you ever had your opinion or</p> <p>7 testimony excluded?</p> <p>8 A. There's been times where a judge</p> <p>9 has ruled that I wouldn't be allowed to</p> <p>10 testify.</p> <p>11 Q. So the answer is yes?</p> <p>12 MR. HAVERTY: No, objection. That's</p> <p>13 not -- the answer is what it is.</p> <p>14 A. Yeah, I mean, I -- I -- the -- the</p> <p>15 way you've asked the question, I -- I don't</p> <p>16 know the exact rulings and how it relates to</p> <p>17 your question, so I'm trying to answer it the</p> <p>18 best way I can.</p> <p>19 Q. So a judge -- your -- you've</p> <p>20 offered opinion testimony, a judge has ruled</p> <p>21 that your opinion testimony will not be</p> <p>22 admitted?</p> <p>23 A. Sure.</p> <p>24 Q. How many times has that happened?</p> <p>25 A. There's been three cases where the</p>
<p style="text-align: right;">Page 40</p> <p>1 W. VIGILANTE</p> <p>2 judge has ruled that my -- I wouldn't be</p> <p>3 allowed to testify. Technically it's four</p> <p>4 cases.</p> <p>5 Q. Have you had, in addition to those</p> <p>6 four cases where you haven't been allowed to</p> <p>7 testify, had your -- the scope of your</p> <p>8 opinions or the scope of your testimony</p> <p>9 limited by a judge?</p> <p>10 A. Yeah, I believe there's been cases</p> <p>11 where I've been allowed to testify, but I may</p> <p>12 not be allowed to testify about certain</p> <p>13 opinions that I had planned to give; whereas</p> <p>14 other opinions I was allowed to give or would</p> <p>15 be allowed to give depending upon the state of</p> <p>16 the case.</p> <p>17 Q. How many times has your opinion</p> <p>18 been limited in that fashion, your opinion</p> <p>19 testimony been limited in that fashion?</p> <p>20 A. I don't know. Maybe a couple.</p> <p>21 Q. Do you know why your opinion</p> <p>22 testimony has been ruled inadmissible in the</p> <p>23 four cases that you described?</p> <p>24 MR. HAVERTY: Objection. It wasn't</p> <p>25 ruled inadmissible. Object to the form of</p>	<p style="text-align: right;">Page 41</p> <p>1 W. VIGILANTE</p> <p>2 the question, but that's fine.</p> <p>3 MR. SCHULTZ: Fine. I -- I can</p> <p>4 rephrase it.</p> <p>5 MR. HAVERTY: Yeah, please.</p> <p>6 MR. SCHULTZ: But let's be -- let --</p> <p>7 let me use your phrase.</p> <p>8 Q. Of the four occasions in which a</p> <p>9 judge has said that he will not allow you to</p> <p>10 testify in his or her courtroom, do you know</p> <p>11 why the judge said that?</p> <p>12 MR. HAVERTY: Better question.</p> <p>13 A. Yes, I -- I think I understand</p> <p>14 why.</p> <p>15 Q. What is your understanding?</p> <p>16 A. One case was in civil court in</p> <p>17 Florida in a trip and fall and the judge ruled</p> <p>18 that it was a veracity issue between the</p> <p>19 plaintiff and defendant, and he wasn't going</p> <p>20 to have any expert testify in court. So when</p> <p>21 plaintiff's ex -- or plaintiff's counsel</p> <p>22 presented my testimony, the judge ruled that</p> <p>23 he wasn't going to allow any expert to</p> <p>24 testify, so I didn't get a chance to testify.</p> <p>25 A case in Federal Court in either</p>

<p style="text-align: right;">Page 42</p> <p>1 W. VIGILANTE</p> <p>2 New York or Connecticut back in maybe the 2004</p> <p>3 time frame a judge found that my opinions were</p> <p>4 not beyond the province of the jury, that the</p> <p>5 field of psychology was nothing more than</p> <p>6 common sense; therefore, he wouldn't let me</p> <p>7 testify in the case.</p> <p>8 I had a case in Federal Court in</p> <p>9 Virginia where the judge found that the hazard</p> <p>10 was an act of God, act of nature; and,</p> <p>11 therefore, my assessment would not be allowed</p> <p>12 to -- and the case would not be allowed to go</p> <p>13 forward.</p> <p>14 Another case in Virginia was</p> <p>15 civil -- State Court where the judge -- it was</p> <p>16 a trip and fall case. A judge ruled that the</p> <p>17 State of Virginia doesn't recognize the field</p> <p>18 or science of human factors; therefore, she</p> <p>19 wouldn't let me testify. The ruling was</p> <p>20 appealed on appeal. The judge's -- trial</p> <p>21 judge's decision was overturned. The</p> <p>22 Appellate Court's decision was appealed to the</p> <p>23 State Supreme Court. The Virginia State</p> <p>24 Supreme Court said that it was in the trial</p> <p>25 judge's discretion; therefore, they let the</p>	<p style="text-align: right;">Page 43</p> <p>1 W. VIGILANTE</p> <p>2 ruling stand without making a comment as to</p> <p>3 whether or not the State of Virginia</p> <p>4 recognized the field of human factors.</p> <p>5 Q. So just so that we're clear on the</p> <p>6 record, in this last case you were describing,</p> <p>7 ultimately the highest court in the State of</p> <p>8 Virginia said the Trial Court properly</p> <p>9 disallowed your testimony?</p> <p>10 MR. HAVERTY: Objection.</p> <p>11 A. That --</p> <p>12 MR. HAVERTY: They ruled that they</p> <p>13 didn't abuse its discretion.</p> <p>14 A. Yeah, it's my -- I'm sorry.</p> <p>15 MR. HAVERTY: Go ahead.</p> <p>16 A. Yeah, my understanding of the</p> <p>17 ruling was the State Supreme Court said it was</p> <p>18 in -- within the Trial Judge's discretion.</p> <p>19 Q. And, therefore, the judge was</p> <p>20 proper in its ruling?</p> <p>21 MR. HAVERTY: Objection, Dave. You</p> <p>22 know that's not what that means.</p> <p>23 A. I don't know what other than what</p> <p>24 I've been told. I'm --</p> <p>25 Q. Okay.</p>
<p style="text-align: right;">Page 44</p> <p>1 W. VIGILANTE</p> <p>2 A. So I can't agree with you or not</p> <p>3 agree with you. I just know that that's what</p> <p>4 the ruling was.</p> <p>5 Q. Have you read the opinions in</p> <p>6 those cases?</p> <p>7 A. I don't know that I ever seen an</p> <p>8 opinion in the -- in that, the Virginia State</p> <p>9 Court either at the Appellate level or the</p> <p>10 State Supreme Court level.</p> <p>11 Q. How about the other ones, the</p> <p>12 other three?</p> <p>13 A. I don't think there was anything</p> <p>14 written in the -- the case down in Florida.</p> <p>15 It was a decision at trial, time of trial.</p> <p>16 The one -- the Daubert challenge in Virginia</p> <p>17 I've -- I've never seen the -- I don't think</p> <p>18 I've seen the -- the ruling, a written ruling.</p> <p>19 And I'm pretty sure at one time I did see that</p> <p>20 a written ruling -- I -- I take that back.</p> <p>21 I'm pretty sure that the case in 2004 in</p> <p>22 Federal Court, I saw the transcript from the</p> <p>23 hearing, the Daubert hearing. I wasn't</p> <p>24 present for it. So I do remember reading the</p> <p>25 transcript at some point in time.</p>	<p style="text-align: right;">Page 45</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay. The Florida case was in</p> <p>3 what court?</p> <p>4 A. It was in State Court somewhere</p> <p>5 near Venice, Florida, which is the west side</p> <p>6 of Florida. I don't know if it was actually</p> <p>7 Venice or -- or -- or maybe Naples. I don't</p> <p>8 -- I don't recall.</p> <p>9 Q. What was the name of the case?</p> <p>10 A. I don't recall the plaintiff, and</p> <p>11 the -- the defendant was something like You Do</p> <p>12 It Aluminum or something like -- of that -- of</p> <p>13 that nature.</p> <p>14 Q. Do you know who the lawyer was on</p> <p>15 the other side of that case?</p> <p>16 A. I do not.</p> <p>17 Q. You were testifying or hoping to</p> <p>18 testify on behalf of the plaintiff in that</p> <p>19 case; correct?</p> <p>20 A. I was retained on behalf of the</p> <p>21 plaintiff in that case.</p> <p>22 Q. Okay. In the second case you said</p> <p>23 it was determined that your testimony would</p> <p>24 not be helpful to the jury. Where was that</p> <p>25 case venued?</p>

<p style="text-align: right;">Page 46</p> <p>1 W. VIGILANTE</p> <p>2 A. Yeah, what I testified to was the</p> <p>3 judge said the field of psychology was nothing</p> <p>4 more than common sense, and my opinions were</p> <p>5 not beyond the province of a jury. That case</p> <p>6 was venued in either Connecticut or New York.</p> <p>7 Q. You don't know which?</p> <p>8 A. I don't recall.</p> <p>9 Q. Federal or State?</p> <p>10 A. Federal.</p> <p>11 Q. Do you know the name of the case?</p> <p>12 A. It's Wald versus Costco.</p> <p>13 (Sneeze.)</p> <p>14 A. God bless you.</p> <p>15 Q. In any event -- and you don't</p> <p>16 understand that ruling to be that the judge</p> <p>17 found that your testimony would not be helpful</p> <p>18 to the jury? You don't understand it that</p> <p>19 way.</p> <p>20 A. I've already told you my</p> <p>21 understanding. The judge in the trial -- in</p> <p>22 the hearing, I should say, commented that the</p> <p>23 field of psychology was nothing more than</p> <p>24 common sense; and the other comment he made</p> <p>25 was that my opinions would not be beyond the</p>	<p style="text-align: right;">Page 47</p> <p>1 W. VIGILANTE</p> <p>2 province of the jury, so he wasn't going to</p> <p>3 let me testify. That's the extent of my -- of</p> <p>4 my knowledge.</p> <p>5 Q. Okay. So you don't understand it</p> <p>6 beyond what you've just said?</p> <p>7 A. That's correct.</p> <p>8 Q. Okay. And in the case in which</p> <p>9 the judge said the incident in question was</p> <p>10 the act of God, I take it you were opining</p> <p>11 that it was not an act of God; correct?</p> <p>12 A. No, there was a -- I was working</p> <p>13 on behalf of the -- of the -- of the</p> <p>14 plaintiffs. There was another expert in the</p> <p>15 case also working on behalf of the plaintiff,</p> <p>16 an engineer, and what our opinions were was</p> <p>17 that the -- the hazard that ended up injuring</p> <p>18 the plaintiff was foreseeable to the</p> <p>19 defendants.</p> <p>20 Q. And so why did the judge exclude</p> <p>21 your opinion?</p> <p>22 A. Yeah, he felt that the opinion --</p> <p>23 that the hazard was an act of God, therefore,</p> <p>24 our analyses and opinions related to them were</p> <p>25 inadmissible because it was a -- it was an act</p>
<p style="text-align: right;">Page 48</p> <p>1 W. VIGILANTE</p> <p>2 of God.</p> <p>3 Q. Okay. Were you taking a position</p> <p>4 that the incident was or wasn't an act of God?</p> <p>5 A. I -- I don't believe I ever took</p> <p>6 that position.</p> <p>7 Q. Okay. What was the hazard</p> <p>8 involved in that case?</p> <p>9 A. The hazard was a -- the case</p> <p>10 involved a pole vault mat used for track and</p> <p>11 field. It was used outdoors where it was</p> <p>12 marketed for on an outdoor track. The school,</p> <p>13 I believe it was a high school, had left the</p> <p>14 pole vault mat out. It was on a -- a --</p> <p>15 what's the best way to describe it? A</p> <p>16 platform, a small -- a short platform to keep</p> <p>17 it out of the mud and the -- the dirt and</p> <p>18 everything to help prevent deterioration of</p> <p>19 the mat.</p> <p>20 The mat was left out during a --</p> <p>21 another event. I think -- I don't remember if</p> <p>22 it was a baseball game or a football game or</p> <p>23 whatever, but a storm came in, a pretty</p> <p>24 powerful storm came in, a thunderstorm came</p> <p>25 in. The crowd was asked to take shelter in</p>	<p style="text-align: right;">Page 49</p> <p>1 W. VIGILANTE</p> <p>2 their cars. As the crowd was making their way</p> <p>3 through the adjacent track and field area, a</p> <p>4 gust of wind came in and picked the pole vault</p> <p>5 mat up and tumbled it down the track and it</p> <p>6 struck multiple people; and one of those</p> <p>7 people were hurt badly, I guess, and that was</p> <p>8 the -- the gist of the case.</p> <p>9 Q. And what was the opinion that you</p> <p>10 gave in that case?</p> <p>11 A. The opinion, I believe, was that</p> <p>12 the manufacturer of the pole vault mat knew or</p> <p>13 should have known that the pole vault mat</p> <p>14 could be lifted and become a projectile under</p> <p>15 heavy winds and foreseeable conditions and</p> <p>16 potentially injure someone.</p> <p>17 Q. And, therefore, should have done</p> <p>18 what?</p> <p>19 A. Provided warning and instruction</p> <p>20 and/or the ability to strap the mat down,</p> <p>21 anchor the mat down, to inform their customers</p> <p>22 or users of the potential hazard and how to</p> <p>23 safeguard against it.</p> <p>24 Q. And where was that case venued?</p> <p>25 A. Virginia.</p>

<p style="text-align: right;">Page 50</p> <p>1 W. VIGILANTE</p> <p>2 Q. Federal Court?</p> <p>3 A. Yes.</p> <p>4 Q. What was the name of the case?</p> <p>5 A. I don't recall the plaintiff's</p> <p>6 name and I don't recall the defendant's name,</p> <p>7 but there's not that many manufacturers of</p> <p>8 pole vaults -- pole vault mats.</p> <p>9 Q. In the fourth case in which the</p> <p>10 Trial Court said that Virginia did not</p> <p>11 recognize the science of human factors, where</p> <p>12 was that case venued --</p> <p>13 A. This is in --</p> <p>14 Q. -- State or Federal Court?</p> <p>15 A. State Court.</p> <p>16 Q. And what district?</p> <p>17 A. I don't recall. It was in, I</p> <p>18 believe, like the Fairfax area, but I'm not a</p> <p>19 hundred percent sure.</p> <p>20 Q. Do you remember the name of the</p> <p>21 parties in that case?</p> <p>22 A. The plaintiff was a man by the</p> <p>23 name of Hovermill, and I'd have to guess at</p> <p>24 how to spell that, other than trying to do it</p> <p>25 through pronunciation. The defendant was Best</p>	<p style="text-align: right;">Page 51</p> <p>1 W. VIGILANTE</p> <p>2 Buy.</p> <p>3 Q. In the pole vault mat case, how</p> <p>4 large was the mat?</p> <p>5 A. It was a standard size pole vault</p> <p>6 mat, so I don't know offhand exactly, but I'm</p> <p>7 going to hazard a guess that it was something</p> <p>8 like eight-feet wide by maybe nine-feet deep.</p> <p>9 Q. And how thick?</p> <p>10 A. I would say over a foot.</p> <p>11 Q. Okay. Any idea how heavy it was?</p> <p>12 A. I don't -- I don't know. I mean,</p> <p>13 it's probably over a hundred pounds easy.</p> <p>14 Exactly how much it weighed, I don't know.</p> <p>15 Q. Okay. Was there any reason why</p> <p>16 the school in that case could not have brought</p> <p>17 the mat indoors?</p> <p>18 A. Had they known of the potential</p> <p>19 hazard, they could have.</p> <p>20 Q. And your --</p> <p>21 A. It's --</p> <p>22 Q. Your opinion was they didn't know</p> <p>23 of the potential hazard?</p> <p>24 A. Yeah, they -- they weren't aware</p> <p>25 of the potential hazard.</p>
<p style="text-align: right;">Page 52</p> <p>1 W. VIGILANTE</p> <p>2 Q. In the other cases where your</p> <p>3 opinion was not -- you were not prohibited</p> <p>4 from testifying about your opinion but rather</p> <p>5 the scope of your opinions were limited, tell</p> <p>6 me about those cases.</p> <p>7 A. I know a case I testified in</p> <p>8 Federal Court in -- over the course of the</p> <p>9 summer where I had opinions related to the --</p> <p>10 the operator manual for a product related to</p> <p>11 the -- the manufacturer's reliance upon it</p> <p>12 solely to provide information. The judge felt</p> <p>13 that since the plaintiff testified that he had</p> <p>14 read the manual, that that opinion wouldn't</p> <p>15 come in.</p> <p>16 Q. Where was that case venued?</p> <p>17 A. Philadelphia.</p> <p>18 Q. Federal Court?</p> <p>19 A. Yes.</p> <p>20 Q. What were the name of the parties</p> <p>21 in that case?</p> <p>22 A. Yazdani was the plaintiff and BMW</p> <p>23 North America was the defendant.</p> <p>24 Q. What was the product involved?</p> <p>25 A. It was a BMW motorcycle.</p>	<p style="text-align: right;">Page 53</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay. Tell me about the other</p> <p>3 cases in which your opinion testimony has been</p> <p>4 limited.</p> <p>5 A. I know there was a case in Montana</p> <p>6 where there was some overlap between my</p> <p>7 opinions and another expert's opinions, and</p> <p>8 the judge said that I could not provide the</p> <p>9 overlap opinions.</p> <p>10 Q. Do you know why?</p> <p>11 A. Redundancy.</p> <p>12 Q. Okay. Was that in Montana Federal</p> <p>13 or State Court?</p> <p>14 A. I believe that was Federal Court.</p> <p>15 Q. Do you know which district in</p> <p>16 Montana or which town in Montana?</p> <p>17 MR. HAVERTY: It's probably the same</p> <p>18 thing.</p> <p>19 MR. SCHULTZ: It's not.</p> <p>20 A. I -- I don't know.</p> <p>21 Q. Okay. Was it Butte?</p> <p>22 A. I can't say whether it was or not.</p> <p>23 Q. Okay. What were the name of the</p> <p>24 parties in that case?</p> <p>25 A. I don't remember the -- the</p>

<p style="text-align: right;">Page 54</p> <p>1 W. VIGILANTE</p> <p>2 plaintiff's name, but the defendant was the</p> <p>3 company that owned Big Sky Ski Resort.</p> <p>4 Q. And what was the opinion that you</p> <p>5 were going to provide but were not allowed to?</p> <p>6 A. I don't recall. Generally my</p> <p>7 opinions were -- were with respect to the</p> <p>8 ability of the plaintiff to discern and react</p> <p>9 to, when she was able to discern a -- a change</p> <p>10 in the run of the ski slope given her position</p> <p>11 on the slope; and then the failure of the ski</p> <p>12 mountain to provide adequate uphill warning to</p> <p>13 the skiers as to the sudden and drastic change</p> <p>14 in the direction of the slope of the -- of the</p> <p>15 run.</p> <p>16 Q. Any other cases in which your</p> <p>17 anticipated testimony was limited?</p> <p>18 A. They're the only ones I can think</p> <p>19 of.</p> <p>20 Q. All right. Have you ever</p> <p>21 testified that an instruction or warning</p> <p>22 provided by a manufacturer was adequate?</p> <p>23 A. I don't know if I've ever</p> <p>24 testified to that or not.</p> <p>25 Q. Have you ever rendered a formal</p>	<p style="text-align: right;">Page 55</p> <p>1 W. VIGILANTE</p> <p>2 opinion to that effect?</p> <p>3 A. I've been hired by manufacturers</p> <p>4 to assess the adequacy of their warning. I</p> <p>5 have had favorable opinions for the defendant</p> <p>6 in some of those cases; and in some of those</p> <p>7 cases I have not been able to render a</p> <p>8 favorable opinion.</p> <p>9 Q. Have you -- have you rendered a</p> <p>10 formal opinion? In other words, one that was</p> <p>11 disclosed to the opposing party in which you</p> <p>12 opined that the instruction or warning</p> <p>13 provided by the manufacturer was adequate?</p> <p>14 A. Yes, and I think I did testify in</p> <p>15 deposition in at least two cases with that</p> <p>16 fact pattern that I -- that I remember the</p> <p>17 specifics of.</p> <p>18 Q. And what did those cases involve?</p> <p>19 What products?</p> <p>20 A. One was a -- a -- a movable gate</p> <p>21 used -- used to create a pen to keep horses or</p> <p>22 livestock in. The second involved a -- I -- I</p> <p>23 don't remember if it was a boiler or a heater</p> <p>24 installed in a -- I don't remember if it was a</p> <p>25 residence or a commercial -- commercial</p>
<p style="text-align: right;">Page 56</p> <p>1 W. VIGILANTE</p> <p>2 building.</p> <p>3 Q. Okay. Where was the first case,</p> <p>4 the movable gate to keep horses in, where was</p> <p>5 that case venued?</p> <p>6 A. I don't recall. I don't recall.</p> <p>7 Q. Do you remember the lawyer or law</p> <p>8 firm who retained you?</p> <p>9 A. Not offhand.</p> <p>10 Oh, I do remember another one.</p> <p>11 Q. Which is?</p> <p>12 A. I just -- well, technically the --</p> <p>13 the report hasn't been disclosed yet. The</p> <p>14 report was written for a disclosure deadline</p> <p>15 beginning of July and something happened with</p> <p>16 the -- on the -- the more legal side of the</p> <p>17 case that has everything moved out for an</p> <p>18 indeterminant amount of time. So technically</p> <p>19 it doesn't meet the criteria of your question,</p> <p>20 but I do re -- I do recall it. I don't know</p> <p>21 why I forgot it.</p> <p>22 Q. Is it -- is it currently pending?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. Do you feel you can</p> <p>25 disclose anything about the name of the</p>	<p style="text-align: right;">Page 57</p> <p>1 W. VIGILANTE</p> <p>2 parties in that case?</p> <p>3 MR. HAVERTY: I don't think you --</p> <p>4 A. Yeah, I don't know.</p> <p>5 MR. HAVERTY: He shouldn't do</p> <p>6 that --</p> <p>7 A. Yeah.</p> <p>8 MR. HAVERTY: -- until it's been</p> <p>9 disclosed.</p> <p>10 A. Yeah, I think that's --</p> <p>11 Q. Has your identity as an expert</p> <p>12 witness been disclosed in that case?</p> <p>13 A. I don't know.</p> <p>14 Q. Okay. Other than those three</p> <p>15 cases, can you think of any others in which</p> <p>16 you have rendered an opinion that a</p> <p>17 manufacturer's warning or instruction was</p> <p>18 adequate?</p> <p>19 A. I do remember another case that I</p> <p>20 gave a videotaped trial testimony in</p> <p>21 involving -- I think it was a skid loader; and</p> <p>22 there was an issue over the sufficiency of the</p> <p>23 information in the manual provided with the --</p> <p>24 with the product.</p> <p>25 Q. And what was your opinion?</p>

1 W. VIGILANTE
2 A. That the plaintiff had sufficient
3 information based upon the information
4 provided by the manufacturer to know what he
5 was doing was improper and could be hazardous.
6 Q. Where was that case venued?
7 A. That was in Pennsylvania. It's --
8 it was in southeast Pennsylvania. I don't
9 know that I can -- I don't know that -- that I
10 know if it was Federal or State Court, and I
11 don't know if I can get it pinned down to a
12 particular county.
13 Q. Who were the parties?
14 A. I don't recall.
15 Q. Who were the lawyers?
16 A. The -- I know the attorney's first
17 name is -- is Bill or William because it's the
18 same as mine; and I don't recall what his last
19 name was other than it started with an M.
20 Q. And how long ago was that case?
21 A. That was before I moved to -- that
22 was when I was living in Lancaster. So I
23 moved to the Philadelphia area in 2010, so
24 sometime before 2010.
25 Q. Okay. It was when you were at

1 W. VIGILANTE
2 Robson Forensics?
3 A. Yes.
4 Q. Okay. How about the case
5 involving the movable gate, when was that?
6 A. I believe that was when I was
7 living in Lancaster as well.
8 Q. So when you were at
9 Robson Forensics?
10 A. Yes.
11 Q. And the case involving a boiler or
12 heater, where was that venued?
13 A. I don't recall.
14 Q. When was the case?
15 A. I was still at Robson, and I don't
16 recall if I was living in Philadelphia or
17 Lancaster.
18 Q. Who were the parties?
19 A. I don't recall.
20 Q. Who were the lawyers?
21 A. I don't recall.
22 Q. Do you keep lists of these
23 engagements?
24 A. I do not.
25 Q. Why not?

1 W. VIGILANTE
2 A. I have never found a need to.
3 Q. You've been asked about these
4 things before in depositions; right?
5 A. I've been asked similar questions,
6 sure.
7 Q. Right. And -- but you didn't find
8 a need to have that information available to
9 the attorneys questioning you?
10 A. The only thing I find a need to do
11 is to -- for Federal cases is to disclose a
12 four-year testimony history. Other than that
13 I don't -- I don't -- I don't think I'm
14 required to do anything beyond that. So when
15 I prepare for a deposition, I actually prepare
16 for the facts of the case that I'm involved
17 in, not what I've done in the -- in the past.
18 Q. Have you ever disclosed this
19 information to a potential client who is
20 seeking to retain you?
21 A. Which information?
22 Q. Information about prior
23 engagements in which you've testified that a
24 manufacturer's warning was adequate.
25 A. I think the -- the best way to

1 W. VIGILANTE
2 answer that is I'm sure that when a client
3 calls me and they ask me -- I'll give you an
4 example.
5 I got contacted Saturday by a
6 client in -- out in the Pittsburgh area that
7 asked me if I had any prior cases relative to
8 what his case was about, and it was a -- kind
9 of a specific area. And I guess part of his
10 decision making was going to be whether he
11 could find a -- an expert that had worked on
12 similar cases in the past, and I hadn't. So I
13 told him I hadn't done that.
14 Q. Okay. But other than those kind
15 of general responses, you've not been asked to
16 provide specific information, for example,
17 copy of your report in the movable gate case
18 to a lawyer or company seeking to retain you?
19 A. That's a yes and no, and I don't
20 mean to be difficult. I don't remember
21 personally doing that where a client has said,
22 "Can I have a copy of that report?" But when
23 I worked for Robson Forensic, they had a -- a
24 Marketing Team, and part of their Marketing
25 Team was they decided a good idea was to put

<p style="text-align: right;">Page 62</p> <p>1 W. VIGILANTE</p> <p>2 old reports up on the website or offer them in</p> <p>3 what they call "the white book" which is</p> <p>4 essentially a three-ring binder with older</p> <p>5 reports on it; and I don't recall if they were</p> <p>6 redacted or if they were full reports. Again,</p> <p>7 I imagine they were redacted. So they would</p> <p>8 have been available to potential clients.</p> <p>9 That's, you know, that's kind of a roundabout</p> <p>10 way of answering your question to make sure I</p> <p>11 did it completely.</p> <p>12 Q. Have you ever turned down a</p> <p>13 litigation engagement on behalf of a plaintiff</p> <p>14 because you felt that the warning or</p> <p>15 instruction provided by the manufacturer was,</p> <p>16 in fact, adequate?</p> <p>17 A. I've had cases where I had to tell</p> <p>18 a client after they retained me that based</p> <p>19 upon my analysis, I -- I couldn't find that</p> <p>20 the warning was inadequate.</p> <p>21 Q. How often has that happened?</p> <p>22 A. Every now and again.</p> <p>23 Q. Usually in the majority of cases</p> <p>24 you find that the warning or instruction was</p> <p>25 not adequate when asked to opine on that topic</p>	<p style="text-align: right;">Page 63</p> <p>1 W. VIGILANTE</p> <p>2 for a plaintiff?</p> <p>3 A. If for the majority of -- of</p> <p>4 plaintiff cases that I'm retained in to assess</p> <p>5 the adequacy of the warning, I would say the</p> <p>6 majority I've been able to find that the</p> <p>7 warning -- or I did find the warning was not</p> <p>8 adequate.</p> <p>9 Q. You -- you were at</p> <p>10 Robson Forensics from 2003 until 2015; is that</p> <p>11 right?</p> <p>12 A. Correct.</p> <p>13 Q. And your title there was</p> <p>14 "associate"; is that right?</p> <p>15 A. Yes.</p> <p>16 Q. And in that 12 years that you were</p> <p>17 there, you never made principal?</p> <p>18 A. Yeah, I never made principal.</p> <p>19 There was only -- when I arrived there, there</p> <p>20 was only the major partner, the founder of the</p> <p>21 firm, Lance Robson, and then two part -- two</p> <p>22 partners that were the area managers in</p> <p>23 Lancaster and Cedar Knolls that each owned 15</p> <p>24 percent of the -- of the company. The</p> <p>25 owner -- the -- the founder owned the bulk</p>
<p style="text-align: right;">Page 64</p> <p>1 W. VIGILANTE</p> <p>2 majority of it and then there was money or</p> <p>3 shares set aside for ESOP, Employee Stock</p> <p>4 Option Program.</p> <p>5 The owner eventually bought those</p> <p>6 two partners out, brought in a CEO or promoted</p> <p>7 a CEO, and when he promoted the CEO, he gave</p> <p>8 that CEO 5 percent of the company. And then</p> <p>9 that was the way the company was owned until</p> <p>10 the founder sold the company to the CEO and</p> <p>11 his wife. And so currently I believe the only</p> <p>12 two shareholders are the CEO and his wife and</p> <p>13 then the ESOP, Employee Stock Option Program.</p> <p>14 Q. Were you in the ESOP?</p> <p>15 A. Yes.</p> <p>16 Q. Did anybody become a principal</p> <p>17 during the time you were there?</p> <p>18 A. Yeah, so if principal you mean</p> <p>19 shareholder, it would have been the CEO and</p> <p>20 his wife.</p> <p>21 Q. Okay. Do you have an</p> <p>22 understanding -- 'cause that -- that phrase is</p> <p>23 used on Robson's website, "principal."</p> <p>24 Do you have an understanding of</p> <p>25 what they mean by that phrase?</p>	<p style="text-align: right;">Page 65</p> <p>1 W. VIGILANTE</p> <p>2 A. Well, I think that Bart Eckhardt</p> <p>3 is the owner of the company now. He bought</p> <p>4 the company. Him and his wife bought the</p> <p>5 shares from Lance Robson a number of years</p> <p>6 ago, maybe two or three, and at that point I</p> <p>7 think he changed his name from CEO/President</p> <p>8 to Principal.</p> <p>9 Q. In your current employment with or</p> <p>10 work with Vigilante Consulting dba Vigilante</p> <p>11 Forensic, other than this one case you</p> <p>12 mentioned, have you ever rendered an opinion</p> <p>13 that a manufacturer's instructions or warnings</p> <p>14 were adequate?</p> <p>15 A. I'm sorry, 'cause you kind of lost</p> <p>16 me in the question.</p> <p>17 Q. Sure. I think you said that since</p> <p>18 the time you formed Vigilante Consulting</p> <p>19 you've rendered one opinion, it hasn't been</p> <p>20 disclosed yet, that a manufacturer's warning</p> <p>21 or instruction was adequate; correct?</p> <p>22 A. I think that's -- I've only been</p> <p>23 retained by one manufacturer defendant since</p> <p>24 August in a product warnings case. I think</p> <p>25 that's accurate.</p>

<p style="text-align: right;">Page 66</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay. Have you been retained --</p> <p>3 other than that one manufacturer, have you</p> <p>4 been retained on behalf of any other</p> <p>5 manufacturers during the time that you've had</p> <p>6 Vigilante Consulting dba Vigilante Forensic?</p> <p>7 A. I don't know. I'm going to say if</p> <p>8 I had, it's been a relatively few times, but</p> <p>9 nothing else is coming to mind.</p> <p>10 Q. Okay. How many engagements do you</p> <p>11 currently have?</p> <p>12 A. I think I assigned something on</p> <p>13 the order of 50 case numbers in 2016. Not all</p> <p>14 those cases have started. Not all those cases</p> <p>15 are active.</p> <p>16 Q. Okay. And to the best of your</p> <p>17 recollection, as you sit here, of those 50</p> <p>18 cases only one is for a defendant</p> <p>19 manufacturer?</p> <p>20 A. I can tell you that there's only</p> <p>21 one that I know for sure. It -- yeah, I</p> <p>22 don't...</p> <p>23 (Exhibit Vigilante-2, multipage</p> <p>24 document entitled The Experts Robson</p> <p>25 Forensic, The Robson Forensic Difference,</p>	<p style="text-align: right;">Page 67</p> <p>1 W. VIGILANTE</p> <p>2 is marked for identification.)</p> <p>3 MR. SCHULTZ: I'm going to mark</p> <p>4 several of them.</p> <p>5 (Pause.)</p> <p>6 MR. HAVERTY: Is that 2?</p> <p>7 (Exhibit Vigilante-3, multipage</p> <p>8 document entitled The Experts Robson</p> <p>9 Forensic, Human Factors &, is marked for</p> <p>10 identification.)</p> <p>11 (Exhibit Vigilante-4, multipage</p> <p>12 document entitled The Experts Robson</p> <p>13 Forensic, Medical Device, is marked for</p> <p>14 identification.)</p> <p>15 MR. SCHULTZ: Go ahead and hand them</p> <p>16 all over.</p> <p>17 MR. HAVERTY: 2, 3, 4; right?</p> <p>18 THE WITNESS: Thank you.</p> <p>19 BY MR. SCHULTZ:</p> <p>20 Q. Mr. Vigilante, the court reporter</p> <p>21 has handed you exhibits marked 2, 3, and 4.</p> <p>22 All of them are various printouts from Robson</p> <p>23 Forensics' website.</p> <p>24 I just want to know if you</p> <p>25 recognize -- would you agree with me that</p>
<p style="text-align: right;">Page 68</p> <p>1 W. VIGILANTE</p> <p>2 that's the Robson Forensics that you worked</p> <p>3 for when you were there from 2002 to 2015?</p> <p>4 A. Yes, it appears to be. They've --</p> <p>5 they've changed their logo it appears to be,</p> <p>6 but this is Robson Forensic.</p> <p>7 Q. Okay. And with respect to -- for</p> <p>8 example, you're looking right now at Exhibit 2</p> <p>9 which has a picture of --</p> <p>10 A. Do you want me to hold it up?</p> <p>11 Q. Sure. Please. That has a picture</p> <p>12 of the current owner of the company; right?</p> <p>13 A. Yes.</p> <p>14 Q. And you recognize him because you</p> <p>15 worked for him; right?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. Earlier in this deposition</p> <p>18 you talked about peer-reviewed research. We</p> <p>19 have, I think, on your CV a list of your</p> <p>20 articles and publications.</p> <p>21 Can you tell me which ones of</p> <p>22 those were peer reviewed?</p> <p>23 A. Everything from Page 5 through</p> <p>24 Page 10.</p> <p>25 Q. Okay. Without exception?</p>	<p style="text-align: right;">Page 69</p> <p>1 W. VIGILANTE</p> <p>2 A. Well, the top of Page 5 has my</p> <p>3 professional memberships -- memberships and</p> <p>4 affiliations, but from --</p> <p>5 Q. Right. I'm just asking about the</p> <p>6 actual articles, though, or the article -- or</p> <p>7 publications.</p> <p>8 A. Yeah, these are all peer-reviewed</p> <p>9 publications and peer-reviewed technical</p> <p>10 reports.</p> <p>11 Q. When you say "peer-reviewed</p> <p>12 technical reports," what do you mean?</p> <p>13 A. Well, "peer review" has different</p> <p>14 meanings to different circumstances. So, for</p> <p>15 example, the publications and presentations on</p> <p>16 Pages 5 through 8 was the traditional academic</p> <p>17 peer review where the article -- the research</p> <p>18 is submitted to a journal or conference. The</p> <p>19 editor of the journal or conference submits it</p> <p>20 to blind peer reviewers who don't know who the</p> <p>21 author is or are not supposed to know who the</p> <p>22 author is and then give feedback to the editor</p> <p>23 as to acceptance, rejection, acceptance with</p> <p>24 qualifications. So that's the typical way</p> <p>25 it's done in academia for scientific journals</p>

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<p>1 W. VIGILANTE 2 and so forth. 3 The technical reports that are 4 listed on Pages 8 through 10 were IBM internal 5 technical reports, and that peer-review 6 process was a little bit different. They were 7 given to other professionals in the -- the 8 department who knew where the technical 9 reports would come from. They were approved 10 by management and so forth before they were 11 released for publication as a technical report 12 in IBM. 13 Q. Okay. So those were all peer 14 reviewed internally at IBM? 15 A. Yes. 16 Q. Okay. I don't have a copy with 17 me, but I suspect you have a copy accessible 18 to you which is the portion of your report 19 that deals with your expert testimony by 20 deposition or trial. 21 Do you have that available to you? 22 A. I'm sorry. What -- 23 Q. Do you have that with you? 24 MR. HAVERTY: List of testimony. 25 Q. Your list of testimony.</p>	<p>1 W. VIGILANTE 2 A. Oh, yes, I do, yeah. 3 Q. By my count you have testified 46 4 times at least as listed in the last four 5 years. 6 Does that sound right to you? 7 A. I'd have to count them, but I mean 8 that's probably -- probably in that ballpark. 9 Q. Which you would roughly plan -- 10 A. I -- I have to -- 11 Q. Oh. Go ahead. 12 A. Just a clarification. I don't 13 know that I have the four-year testimony 14 history that was submitted with the report. I 15 have the updated one, so I'm happy to produce 16 that too. When I was preparing for the 17 deposition, I change them as I go through 18 depositions and so forth, so they're updated; 19 and I don't know that -- this report was 20 submitted in April and my current date on my 21 list is August, so there's probably some 22 change. 23 Q. Okay. Well, why don't you, as 24 you're looking at your current testimony, what 25 testimony do you have since April of 2016?</p>
Page 72	Page 73
<p>1 W. VIGILANTE 2 A. There was a Denise Pender versus 3 Florida East Coast Railway in April. 4 Joseph and Ursy Vitale versus 5 Electrolux Home Products in April. 6 Anita Malone versus K&G Mens 7 Company. 8 Q. Hold on. Yeah. I'm sorry. You 9 just got to go a little bit slower. 10 A. Sure. 11 Q. Yeah, why don't we -- why don't 12 we -- I'll tell you what, why don't we do 13 this? Why don't we, if you're willing to, 14 just mark a copy of that at a break. 15 A. Sure, absolutely. 16 Q. Okay. In general, though, you 17 would agree that by these numbers you are on 18 average testifying at a deposition or a trial 19 about once a month; correct? 20 A. Yeah, I mean, I do about 12 21 depositions a year. I -- I -- maybe sometimes 22 a little more, sometimes a little bit less. 23 That's probably about right. 24 Q. Do you hold -- other than a 25 driver's license, do you hold any licenses of</p>	<p>1 W. VIGILANTE 2 any kind in ergonomics or human factors? 3 A. I'm not aware of any licenses. 4 I'm aware of the certification through the 5 Board of Certification For -- 6 Q. Right. 7 A. -- Professional Ergonomists. 8 Q. All right. Have you ever been 9 terminated from a position as a human factors 10 professional or an ergonomics professional? 11 A. No. 12 Q. Have you ever been relieved of an 13 engagement as an expert witness by your 14 client? 15 A. I think I know what you mean, so 16 any time the case is over, I'm released. But 17 I've been involved in cases where I can't give 18 a favorable opinion that I'm asked by the 19 client not to do any more work, so I submit a 20 final bill and -- and that's it. I typically 21 close the case. So that happens. 22 Q. Other than those two circumstances 23 when you are unable to give a helpful opinion 24 or the case ends, have you ever been -- I 25 mean, let me put it in sort of common</p>

<p style="text-align: right;">Page 74</p> <p>1 W. VIGILANTE</p> <p>2 parlance. Have you ever been fired by a</p> <p>3 client?</p> <p>4 A. Not -- no.</p> <p>5 Q. Let's talk about your medical</p> <p>6 device experience in particular.</p> <p>7 You -- you've never been employed</p> <p>8 by a medical device manufacturer; correct?</p> <p>9 A. No. I'm sorry. Correct.</p> <p>10 Q. Correct. Okay. And you've never</p> <p>11 been hired by the Food and Drug Administration</p> <p>12 to consult on any medical devices?</p> <p>13 A. Not on any medical devices.</p> <p>14 Q. Okay. Are you -- have you been</p> <p>15 retained by the Food and Drug Administration</p> <p>16 to consult regarding pharmaceuticals?</p> <p>17 A. I've never been hired, but I have</p> <p>18 worked in consultation with the FDA on</p> <p>19 research related to pharmaceuticals.</p> <p>20 Q. How many times?</p> <p>21 A. I did two large projects that I</p> <p>22 cooperated with the FDA on. One was on</p> <p>23 formatting features and factors for</p> <p>24 over-the-counter medication labeling.</p> <p>25 Q. Formatting what? I'm sorry.</p>	<p style="text-align: right;">Page 75</p> <p>1 W. VIGILANTE</p> <p>2 A. Features, design features,</p> <p>3 presentation of information on</p> <p>4 over-the-counter medication labeling. That</p> <p>5 was in the mid to the late '90s.</p> <p>6 And then I worked on a -- well, my</p> <p>7 dissertation was on the presentation of risk</p> <p>8 and benefit information on direct-to-consumer</p> <p>9 advertisements of prescription medications on</p> <p>10 the web, and I was -- that was for my</p> <p>11 dissertation.</p> <p>12 Q. Okay. Did the FDA have some</p> <p>13 involvement in your dissertation?</p> <p>14 A. Yes. After -- the lab I worked in</p> <p>15 at North Carolina State University, the</p> <p>16 Cognitive Ergonomics Lab, we did a lot of</p> <p>17 research in warnings and risk perception; and</p> <p>18 one area was that a significant area of work</p> <p>19 done by the lab was related to medication</p> <p>20 labeling and presentation of information for</p> <p>21 over-the-counter prescription medications.</p> <p>22 So in the '90s we were working</p> <p>23 with the FDA on areas in which they wanted</p> <p>24 research done. So it was a way to come up</p> <p>25 with research projects that would be useful,</p>
<p style="text-align: right;">Page 76</p> <p>1 W. VIGILANTE</p> <p>2 you know, in the real world. So we did a</p> <p>3 number of studies related to the formatting</p> <p>4 features of over-the-counter medication</p> <p>5 labeling and the ordering of information</p> <p>6 presented on over -- over-the-counter</p> <p>7 medication labeling. The results of that</p> <p>8 information was fed back to the FDA and used</p> <p>9 in their regulatory process to come up with</p> <p>10 requirements for the presentation of</p> <p>11 information on over-the-counter medication</p> <p>12 labeling which, I believe, they put forth in</p> <p>13 1999.</p> <p>14 After doing the OTC stuff, we were</p> <p>15 looking for other projects; and our contacts</p> <p>16 at the FDA, in consultation with them, asked</p> <p>17 them if -- asked us if we can do work related</p> <p>18 to direct-to-consumer advertisements because</p> <p>19 in the late '90s that was becoming -- I think</p> <p>20 there was a change in the regulation or the</p> <p>21 law allowing pharmaceutical companies to</p> <p>22 advertise directly to consumers, and there was</p> <p>23 a question over how they were doing that and</p> <p>24 how they were presenting risk and hazard</p> <p>25 information and compared to the benefits</p>	<p style="text-align: right;">Page 77</p> <p>1 W. VIGILANTE</p> <p>2 because there was some loose interpretation of</p> <p>3 the equal time clause in the -- in the new</p> <p>4 regulations. So as a lab we looked at</p> <p>5 direct-to-consumer ads on the web which was</p> <p>6 the hunk of research that I was running, but</p> <p>7 also in print ads and also on television ads.</p> <p>8 So colleagues of mine at NC State</p> <p>9 led the -- a different person lead the</p> <p>10 television advertisements and a third led the</p> <p>11 research done on the print ads. And then</p> <p>12 when -- as we were finding our -- coming to</p> <p>13 our findings, we were feeding that back in to</p> <p>14 our contacts at the FDA for use in their</p> <p>15 regulatory process.</p> <p>16 Q. Okay. Let me drill down on those</p> <p>17 for a second.</p> <p>18 First of all, you've identified</p> <p>19 two projects, right, one with formatting</p> <p>20 features on the labels attached to</p> <p>21 over-the-counter medications themselves;</p> <p>22 right?</p> <p>23 A. Well, I would say there was two</p> <p>24 areas of work that we did. One was DT -- DTC,</p> <p>25 direct-to-consumer advertisement, and the</p>

<p style="text-align: right;">Page 78</p> <p>1 W. VIGILANTE</p> <p>2 other was over-the-counter medication</p> <p>3 labeling.</p> <p>4 Q. Okay.</p> <p>5 A. They -- they both had multiple</p> <p>6 projects within those two areas.</p> <p>7 Q. Both of those projects or both of</p> <p>8 those areas were in the 1990s; correct?</p> <p>9 A. The OTC stuff was mid '90s to late</p> <p>10 '90s. The DTC stuff was late '90s, early</p> <p>11 2000s. I think my dissertation was published</p> <p>12 in 2001 if I'm not mistaken.</p> <p>13 Q. Okay. And since that time --</p> <p>14 A. And then --</p> <p>15 Q. -- since the pub --</p> <p>16 A. -- the -- the other -- I mentioned</p> <p>17 the other colleagues. They finished their</p> <p>18 research and their dissertation and their</p> <p>19 degrees after I did, so I don't know if it was</p> <p>20 2002, 2003, 2004.</p> <p>21 Q. But after your dissertation, you</p> <p>22 did not continue with the projects, did you?</p> <p>23 A. I think I have a publication</p> <p>24 related to the medications, it was after my</p> <p>25 dissertation. Give me a second. I can look</p>	<p style="text-align: right;">Page 79</p> <p>1 W. VIGILANTE</p> <p>2 that up if you don't mind.</p> <p>3 I did a -- I published an article,</p> <p>4 a research paper in 2003, two years -- a year</p> <p>5 and a half, two years after completing my</p> <p>6 Ph.D. and publishing the dissertation on "The</p> <p>7 effects of label format on knowledge</p> <p>8 acquisition and perceived readability by</p> <p>9 younger and older adults."</p> <p>10 Q. For over-the-counter medications?</p> <p>11 A. That would have been for</p> <p>12 over-the-counter.</p> <p>13 Q. And that -- that particular</p> <p>14 article was based upon the research you had</p> <p>15 done as part of your graduate work for a</p> <p>16 dissertation; correct?</p> <p>17 A. No, 'cause the work I did my</p> <p>18 dissertation was on direct-to-consumer</p> <p>19 advertising.</p> <p>20 Q. It was based on work that you did</p> <p>21 as a graduate student?</p> <p>22 A. I was a graduate student at the</p> <p>23 time. The -- I did present and publish</p> <p>24 another paper in 2005 related to</p> <p>25 direct-to-consumer medication advertisement,</p>
<p style="text-align: right;">Page 80</p> <p>1 W. VIGILANTE</p> <p>2 and my guess is, is that was probably based</p> <p>3 upon work I was doing for my dissertation.</p> <p>4 Sometimes there's a lag between finishing the</p> <p>5 work, getting the dissertation done, the</p> <p>6 technical reports done and then getting it</p> <p>7 published. It's harder to get it published in</p> <p>8 a peer-reviewed journal, so it sometimes takes</p> <p>9 longer and there's a lag.</p> <p>10 Then I did a project with -- in</p> <p>11 2007 on direct-to-consumer prescription drug</p> <p>12 advertisement on television and online</p> <p>13 purchases of medications. That was not</p> <p>14 related to my dissertation.</p> <p>15 Q. Was the FDA involved in that</p> <p>16 project?</p> <p>17 A. I don't know.</p> <p>18 Q. Okay. Going back to the</p> <p>19 formatting labels on over-the-counter</p> <p>20 medication that was done in 1990s, mid to late</p> <p>21 '90s, first of all, that was when you were a</p> <p>22 graduate student; right?</p> <p>23 A. I was going to say there was</p> <p>24 another post-dissertation research publication</p> <p>25 in 2005. That one was, again, related to DTC</p>	<p style="text-align: right;">Page 81</p> <p>1 W. VIGILANTE</p> <p>2 information on websites.</p> <p>3 Q. Direct to consumer?</p> <p>4 A. Correct. But a -- a student that</p> <p>5 was helping me with the project, a junior</p> <p>6 student at the time continued that work, and I</p> <p>7 believe that I helped him with his</p> <p>8 continuation of work after, you know,</p> <p>9 graduating and moving on and what have you;</p> <p>10 and that's -- my part in that was published in</p> <p>11 2005, I believe.</p> <p>12 Q. So going back -- let's -- let's</p> <p>13 break this down. Going back to the work you</p> <p>14 did with respect to over-the-counter labeling</p> <p>15 in the mid to late 1990s, that was work you</p> <p>16 did as a graduate student?</p> <p>17 A. Yes.</p> <p>18 Q. So you were doing it under the</p> <p>19 supervision of a faculty member at North</p> <p>20 Carolina State?</p> <p>21 A. Sure. I had an academic advisor.</p> <p>22 Q. Okay. Did you have a contract</p> <p>23 with the FDA?</p> <p>24 A. No.</p> <p>25 Q. Did the institution have a</p>

<p style="text-align: right;">Page 82</p> <p>1 W. VIGILANTE 2 contract with the FDA? 3 A. I don't believe so. 4 Q. Did the FDA sponsor that research? 5 A. They did not sponsor it in that 6 they provided monetary value for it. Again, 7 we were in consultation with them. I believe 8 that the Drug Information Association funded 9 the projects for the OTC stuff and then 10 provided some funding for the -- the 11 direct-to-consumer advertisement research that 12 we did after the OTC stuff -- 13 Q. And what's -- 14 A. -- or at the end of the OTC stuff. 15 Q. What's the Drug Information 16 Association? 17 A. My understanding it was a 18 consortium of manufacturers in the 19 pharmaceutical industry. 20 Q. Okay. So if I understand this 21 right, the Drug Information Association had 22 research performed, I assume, probably not 23 just at North Carolina State, correct -- 24 A. I -- I -- 25 Q. -- as far as you know?</p>	<p style="text-align: right;">Page 83</p> <p>1 W. VIGILANTE 2 A. Yeah, I don't know. 3 Q. Okay. 4 A. But they were -- I believe we 5 submitted a request for grant money -- 6 Q. From the DIA? 7 A. -- to the DIA. 8 Q. Yep. 9 A. And then we had received monies 10 for the OTC stuff and the direct-to-consumer 11 advertisement stuff, and that's -- that's all 12 I could recall. 13 Q. Okay. And so the studies were 14 done -- funded by the DIA, and not requested 15 by the FDA; correct? 16 A. No. Well, two things. The DIA 17 money was not enough to fully fund all the 18 projects. It was used to help purchase some 19 equipment that was used in the multiple 20 studies, but it wasn't -- typically like if 21 you get a grant researching a specific topic, 22 you can apply to a -- a grant organization, 23 maybe the Federal government, and they can 24 provide you with enough money to fund the 25 project fully where they're -- they're paying</p>
<p style="text-align: right;">Page 84</p> <p>1 W. VIGILANTE 2 for the research work, the researchers. 3 They're paying for the -- the lead 4 investigator to maybe not take some classes, 5 not teach some classes. They pay for the -- 6 the participants. They pay for all the 7 equipment. They may pay for travel to present 8 the data and the information. So that's kind 9 of a fully funded grant, a fully funded 10 project under a grant. 11 The DIA did not provide us fully 12 funded grant money. They provided us grant 13 money to help run the projects. So there was 14 multiple projects going on. So I just wanted 15 to make that clear. 16 Second part is, is that the work 17 was done in conjunction with our contacts at 18 the FDA asking them what type of issues do 19 they -- do they see, what type of research is 20 needed, what are ideas for research projects. 21 So that was the extent of our collaboration 22 with the FDA; and then, of course, feeding 23 that data back to the FDA, our contacts at the 24 FDA for their use in whatever they were doing. 25 Q. The FDA did not solicit the</p>	<p style="text-align: right;">Page 85</p> <p>1 W. VIGILANTE 2 research; correct? 3 A. I can tell you -- I don't know. I 4 can tell you that for my direct-to-consumer 5 project -- 6 Q. Right now we're not talking about 7 direct-to-consumer. Okay? Right now my 8 questions are related to the over-the-counter 9 labeling. Okay? 10 A. Yeah. I'm -- I'm sorry. So at -- 11 at that -- the over-the-counter labeling, I 12 don't -- I don't recall. I can tell you how 13 the DTC stuff got started. 14 Q. We'll get to that. 15 A. Yeah. 16 Q. Okay. As far as you know, the FDA 17 did not solicit the research; correct? 18 A. I don't know. 19 Q. Okay. And you don't know because 20 the research was overseen by and requested by 21 the DIA; correct? 22 MR. HAVERTY: Objection. 23 A. No. That's not correct. 24 Q. It was not requested by the DIA? 25 A. Yeah, no, what I just explained is</p>

<p style="text-align: right;">Page 86</p> <p>1 W. VIGILANTE</p> <p>2 that we put in a grant request to the DIA for</p> <p>3 the research topics that we had come up with</p> <p>4 it and they provided us money to partially</p> <p>5 fund the projects. The topics came up in</p> <p>6 conjunction with discussions with the FDA and</p> <p>7 the contacts we had at the FDA. So that's --</p> <p>8 I think that's the, you know, the overall</p> <p>9 history of it.</p> <p>10 Q. When you say the context we --</p> <p>11 "contacts we had at the FDA," who's the "we"</p> <p>12 in that sentence, North Carolina State</p> <p>13 University?</p> <p>14 A. Well, I would have been through</p> <p>15 contacts with it through my advisor, Mike</p> <p>16 Wogalter at the time; and then I had two</p> <p>17 contacts in -- I was trying to explain -- with</p> <p>18 the DTC. When I was looking for a</p> <p>19 dissertation subject I contacted them. I</p> <p>20 said, "Hey, it's Bill Vigilante, you know, I'm</p> <p>21 looking to put together a dissertation. Do</p> <p>22 you have areas of study that you think would</p> <p>23 be of interest and use to the FDA," and that's</p> <p>24 where they -- they pointed -- pointed us into</p> <p>25 the DTC stuff.</p>	<p style="text-align: right;">Page 87</p> <p>1 W. VIGILANTE</p> <p>2 Q. I'll get to the DTC stuff in a</p> <p>3 second. I'm still focussing on the</p> <p>4 over-the-counter labeling. Okay?</p> <p>5 A. Sure.</p> <p>6 Q. Okay. That research was not</p> <p>7 directed by FDA.</p> <p>8 A. Yeah, there was no directive that</p> <p>9 said "You must do this." Again, it was in</p> <p>10 collaboration, discussions with the FDA as to</p> <p>11 what research and what things they were doing</p> <p>12 and research they could use; and that's how we</p> <p>13 decided on research projects.</p> <p>14 Q. Well, and when you say</p> <p>15 "collaboration," that collaboration was</p> <p>16 initiated not by FDA but by North Carolina</p> <p>17 State University; right?</p> <p>18 A. Yeah, I said three times I don't</p> <p>19 know.</p> <p>20 Q. Okay. It was not -- and that</p> <p>21 collaboration -- well, did you deal directly</p> <p>22 with the FDA?</p> <p>23 A. For the OTC stuff, at the latter</p> <p>24 part of the project, I did, but not at the</p> <p>25 start of the project.</p>
<p style="text-align: right;">Page 88</p> <p>1 W. VIGILANTE</p> <p>2 Q. What was the nature of your direct</p> <p>3 dealings with FDA at the latter part of the</p> <p>4 OTC project?</p> <p>5 A. Well, one of the things that I did</p> <p>6 was send them my research; and then back in</p> <p>7 2003, I think the fall of 2003 my contact</p> <p>8 asked me to come and give a -- a presentation</p> <p>9 to the FDA and the committee that was sitting</p> <p>10 for the OTC stuff. So I put together a</p> <p>11 presentation. I sent it down to them and</p> <p>12 unfortunately I -- I came down with a stomach</p> <p>13 bug, so my -- a colleague of mine who was down</p> <p>14 there giving another presentation gave my --</p> <p>15 gave my presentation as well.</p> <p>16 Q. Okay. And that presentation</p> <p>17 involved whatever the outcome of your research</p> <p>18 was?</p> <p>19 A. Yes, in the -- whatever the</p> <p>20 findings from the research was, and I -- I</p> <p>21 don't recall at the time if that was DTC or</p> <p>22 OTC. I just don't recall.</p> <p>23 Q. Okay. And you don't know what FDA</p> <p>24 did internally with your research?</p> <p>25 A. For the DTC stuff, I don't. For</p>	<p style="text-align: right;">Page 89</p> <p>1 W. VIGILANTE</p> <p>2 the OTC stuff I know that it was directly</p> <p>3 implemented in their regulations for the</p> <p>4 labeling. For example, I know that there's a</p> <p>5 requirement for a minimum of 8 point font.</p> <p>6 That came directly out of our research. That</p> <p>7 was one of our recommendations. There was</p> <p>8 a -- an order of the -- of the information, an</p> <p>9 ordering of the information to be presented on</p> <p>10 the labels; and I do know that it was followed</p> <p>11 directly on the result of my research except</p> <p>12 for the presentation of active ingredients,</p> <p>13 that they got pushback from the pharmacists</p> <p>14 and the doctors. They wanted that higher in</p> <p>15 the list. And I know of no other research in</p> <p>16 the country that was done on the -- the</p> <p>17 ordering of information for</p> <p>18 direct-to-consumer -- or over-the-counter</p> <p>19 medication labeling.</p> <p>20 There is recommendations for white</p> <p>21 space that came out of the research that was</p> <p>22 put into the regulations. There was the</p> <p>23 recommendation for foldout labels to present</p> <p>24 or have larger real estate to present the</p> <p>25 information in a more and better format using</p>

<p style="text-align: right;">Page 90</p> <p>1 W. VIGILANTE</p> <p>2 bullet lists, using extra white space, using</p> <p>3 relatively larger fonts, et cetera; and,</p> <p>4 again, that was something that wasn't directly</p> <p>5 from our recommendations that were -- were put</p> <p>6 forth by the FDA and is used now.</p> <p>7 Q. Did you say "directly from your</p> <p>8 research" or "not directly from your</p> <p>9 research"?</p> <p>10 A. It --</p> <p>11 Q. I just didn't hear you.</p> <p>12 A. At what point?</p> <p>13 Q. Just now you said and that -- that</p> <p>14 the FDA took that directly from your research</p> <p>15 or not directly from your research. I just</p> <p>16 didn't hear you.</p> <p>17 A. Yeah, the rec -- the</p> <p>18 recommendation was directly from our</p> <p>19 research --</p> <p>20 Q. Okay.</p> <p>21 A. -- with regard to those topics.</p> <p>22 Q. Do you know if it was exclusively</p> <p>23 from your research?</p> <p>24 A. I don't know of any other research</p> <p>25 that was published related to those topics</p>	<p style="text-align: right;">Page 91</p> <p>1 W. VIGILANTE</p> <p>2 other than what we were doing --</p> <p>3 Q. Well, whether published --</p> <p>4 A. -- and that I was doing at the</p> <p>5 time.</p> <p>6 Q. -- or not, do you know whether it</p> <p>7 came exclusively from your research?</p> <p>8 A. Yeah, I can't say that a --</p> <p>9 another organization somewhere had results</p> <p>10 that they didn't publish to the public that</p> <p>11 were submitted to the -- to the FDA, but I'm</p> <p>12 not aware of it.</p> <p>13 Q. Okay. There's no reason why you</p> <p>14 would be aware of them, is there, if</p> <p>15 information was given to the FDA?</p> <p>16 A. If it was non-public information</p> <p>17 that was given to the FDA, I can't say that</p> <p>18 I'm sure they would send it over to us. Maybe</p> <p>19 it was confidential if it existed. I would</p> <p>20 think that if it was presented to the FDA and</p> <p>21 it wasn't confidential, they would send it up</p> <p>22 to us to at least take a look at to let us</p> <p>23 know what other people were doing. Typically</p> <p>24 that's how research works. You want to be</p> <p>25 able to collaborate between different groups</p>
<p style="text-align: right;">Page 92</p> <p>1 W. VIGILANTE</p> <p>2 and parties so that you're not stepping on</p> <p>3 each other's toes, you get an idea of what's</p> <p>4 being done, pitfalls that may be out there</p> <p>5 that may need to be addressed and so forth.</p> <p>6 Q. Typically that's how FDA research</p> <p>7 is done, is that your testimony?</p> <p>8 A. No, that's typically how research</p> <p>9 is done.</p> <p>10 Q. Right. But you don't know how,</p> <p>11 typically, FDA research is done?</p> <p>12 A. I don't know how it was -- for the</p> <p>13 work that we were doing on the OTC and DTC</p> <p>14 stuff, I don't know how the FDA was getting</p> <p>15 information from other parties and if there</p> <p>16 was information from other parties that</p> <p>17 related -- related to the topics that we were</p> <p>18 working on.</p> <p>19 Q. And in any event, the</p> <p>20 recommendations that were in your research</p> <p>21 related to the font size, the order of</p> <p>22 present -- and I'm talking again about the OTC</p> <p>23 project -- the font size, the order of</p> <p>24 presentation and the amount of white space --</p> <p>25 MR. HAVERTY: Objection.</p>	<p style="text-align: right;">Page 93</p> <p>1 W. VIGILANTE</p> <p>2 Q. -- correct?</p> <p>3 MR. HAVERTY: There's more.</p> <p>4 A. Yeah, so we looked at the font</p> <p>5 size. We looked at the white spacing. We</p> <p>6 looked at using bulleted list versus paragraph</p> <p>7 prose. We looked at extended label designs.</p> <p>8 We looked at even leading between the --</p> <p>9 between the lines which is related to -- to</p> <p>10 white space and the ordering of information.</p> <p>11 Q. Okay. On the direct-to-consumer</p> <p>12 marketing materials, your part of the research</p> <p>13 was related to TV advertisements?</p> <p>14 A. I did help in the TV</p> <p>15 advertisements, but my major project was on</p> <p>16 website advertisements.</p> <p>17 Q. Oh, okay. And was that research</p> <p>18 requested by FDA?</p> <p>19 A. Yeah, so what happened was is that</p> <p>20 I contacted the FDA, my contacts at the FDA,</p> <p>21 and asked them, you know, what areas --</p> <p>22 because we had done the OTC stuff, that was</p> <p>23 behind us, what areas they saw and had need of</p> <p>24 in the future and they requested that I focus</p> <p>25 on the DTC stuff, the direct-to-consumer</p>

<p style="text-align: right;">Page 94</p> <p>1 W. VIGILANTE</p> <p>2 advertisement stuff and we -- in particularly</p> <p>3 the -- the websites for the project I was</p> <p>4 doing.</p> <p>5 Q. You initiated the contact with</p> <p>6 FDA. They didn't initiate it with you.</p> <p>7 A. I know that I -- I initiated that</p> <p>8 contact, yes.</p> <p>9 Q. Okay. And was that research on</p> <p>10 direct-to-consumer advertising on websites</p> <p>11 sponsored in any way by FDA?</p> <p>12 A. Yeah, I don't know. I don't think</p> <p>13 it was sponsored quote-unquote by the FDA.</p> <p>14 Q. Okay. What did you do with your</p> <p>15 research with respect to providing it to FDA?</p> <p>16 A. When I collected the data,</p> <p>17 analyzed the data, I sent them copies of the</p> <p>18 reports, talked to them about it and -- and</p> <p>19 then published the data in peer-reviewed</p> <p>20 journals over a number of years I guess.</p> <p>21 Q. Do you know what use they made of</p> <p>22 your research that you sent to them?</p> <p>23 A. Not specifically. I did -- I do</p> <p>24 know that the requirements for the TV ads</p> <p>25 because I -- I don't typically -- as a --</p>	<p style="text-align: right;">Page 95</p> <p>1 W. VIGILANTE</p> <p>2 after graduate school and after doing my work,</p> <p>3 I don't typically surf direct-to-consumer</p> <p>4 advertisement websites for prescription</p> <p>5 medications, but I do see the advertisements</p> <p>6 on the TV and I know they -- they -- the way</p> <p>7 in which the risks and benefits are presented</p> <p>8 on the TV ad have changed based upon updated</p> <p>9 regulations from the FDA.</p> <p>10 Q. You didn't do the TV research.</p> <p>11 A. I helped in the TV research, but I</p> <p>12 wasn't the -- the major or principal</p> <p>13 researcher on it.</p> <p>14 Q. What was specifically your role</p> <p>15 with respect to the TV research for</p> <p>16 direct-to-consumer advertising --</p> <p>17 A. Yeah, I would --</p> <p>18 Q. -- of pharmaceuticals?</p> <p>19 A. -- have been -- yeah, I'm sorry.</p> <p>20 I would have been working with the -- the</p> <p>21 other principals, the other -- I want to call</p> <p>22 them older grad students that were responsible</p> <p>23 for the projects and coming up with</p> <p>24 methodologies, coming up and reviewing</p> <p>25 questionnaire questions, their surveys, how</p>
<p style="text-align: right;">Page 96</p> <p>1 W. VIGILANTE</p> <p>2 they're going to go about doing the research,</p> <p>3 helping them with the data analysis, and then</p> <p>4 helping them with -- with writing it up.</p> <p>5 Q. Were those direct-to-consumer --</p> <p>6 well, strike that.</p> <p>7 Let's move on to your experience</p> <p>8 back to medical devices.</p> <p>9 You've never been retained by FDA</p> <p>10 or consulted by FDA with respect to medical</p> <p>11 devices; correct?</p> <p>12 A. That's correct.</p> <p>13 Q. Okay. In your traditional</p> <p>14 consulting role at Robson Forensics, were you</p> <p>15 ever retained by a medical device</p> <p>16 manufacturer?</p> <p>17 A. No.</p> <p>18 Q. Did you ever participate in design</p> <p>19 validation of a medical device under the Code</p> <p>20 of Federal Regulations, 21 CFR Section 820.30?</p> <p>21 A. No.</p> <p>22 Q. Did you ever --</p> <p>23 A. Excuse me.</p> <p>24 Q. No, I'm sorry. You've answered my</p> <p>25 question --</p>	<p style="text-align: right;">Page 97</p> <p>1 W. VIGILANTE</p> <p>2 MR. HAVERTY: No, no.</p> <p>3 Q. -- Mr. Vigilante.</p> <p>4 MR. HAVERTY: Go ahead.</p> <p>5 A. Yeah, so I just want --</p> <p>6 MR. SCHULTZ: No, no, no, no. It's</p> <p>7 my deposition.</p> <p>8 MR. HAVERTY: Dave. Excuse me,</p> <p>9 Dave. He -- he's talk --</p> <p>10 MR. SCHULTZ: He's answered. It was</p> <p>11 a yes-or-no question.</p> <p>12 MR. HAVERTY: Dave, he said no and</p> <p>13 now he realized that that was not a correct</p> <p>14 answer. He's entitled to finish.</p> <p>15 Q. Oh, is that not a correct answer?</p> <p>16 A. Well, what I was going to say --</p> <p>17 it's a correct answer. What I was going to --</p> <p>18 Q. Okay.</p> <p>19 A. -- is I need a break. So whether</p> <p>20 you want to do it right now or you want to do</p> <p>21 it after the next question, either way I'm</p> <p>22 happy to oblige you, but I need a break.</p> <p>23 MR. SCHULTZ: You need a break,</p> <p>24 that's fine.</p> <p>25 THE VIDEOGRAPHER: We are now going</p>

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1 W. VIGILANTE
2 off the video record. That concludes DVD
3 Number 1. The time is 11:49.

4 (A recess is held from 11:49 a.m. to
5 12:02 p.m.)

6 THE VIDEOGRAPHER: We are now back
7 on the video record. This commences DVD
8 Number 2, August 18th, 2016. The time,
9 12:02.

10 BY MR. SCHULTZ:

11 Q. Mr. Vigilante, before the break we
12 were talking about the design validation
13 regulations in the Code of Federal Regulations
14 for medical devices. And with respect to
15 those regulations, have you ever performed a
16 risk analysis pursuant to those regulations?

17 A. I have not.

18 Q. Have you ever submitted labeling
19 of a medical device to FDA pursuant to
20 21 CFR 801?

21 A. No.

22 Q. Ever been involved in the process
23 of submitting a 510(k) application for
24 clearance of a medical device to FDA?

25 A. No.

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1 W. VIGILANTE

2 Q. How about involved in the process
3 of submitting a pre-market approval
4 application to FDA for a medical device?

5 A. I have not.

6 Q. Have you ever drafted a warning or
7 label or instruction for a medical device
8 manufacturer?

9 A. I have not.

10 Q. Have you ever been involved in a
11 CAPA process?

12 A. No.

13 Q. Ever been involved in a
14 post-market surveillance program for a medical
15 device?

16 A. I have not.

17 Q. Or developed a post-market
18 surveillance plan under the Federal
19 regulations?

20 A. I have not.

21 Q. Have you had any consulting,
22 traditional consulting role with respect to
23 medical devices?

24 A. Are you asking me if I've ever
25 been retained by a manufacturer in a

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1 W. VIGILANTE
2 consulting role for a medical device?

3 Q. Yes.

4 A. I have not.

5 Q. Okay. Or just to be clear and
6 complete, work on a project for someone who
7 was retained by a medical device manufacturer.

8 A. That one gets a little bit more
9 fuzzy.

10 Q. Okay. Why don't you explain that
11 to me?

12 A. I had a -- a colleague at Robson
13 that was doing some medical device submission
14 work, testing work, submission work, and she
15 used to get overloaded in her work and she
16 would ask colleagues to help her go through
17 data or whatever, and I've -- I've helped her
18 on those parts, but I can't really get into
19 exactly what it was that I was reviewing or
20 doing for her at the time. I just don't
21 recall.

22 Q. It was a number of years ago?

23 A. Yes.

24 Q. And it was reviewing data?

25 A. I don't recall all the tasks.

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1 W. VIGILANTE

2 Q. Okay. But it was a project that
3 was -- someone else at Robson was retained to
4 do for the medical device manufacturer?

5 A. Yes.

6 Q. All right. In your litigation
7 work, whether at Robson or at Vigilante
8 Forensics, have you ever been hired by a
9 medical device manufacturer?

10 A. None are coming to mind.

11 Q. Okay. Other than this case, have
12 you ever been retained on behalf of a
13 plaintiff suing a medical device manufacturer?

14 A. None are coming to mind, but I
15 have a -- a feeling that I did at least
16 consult on one case involving a medical
17 product, but it's very, very fuzzy, and I
18 don't have a specific memory of it.

19 Q. Okay. So it's not -- it's not
20 certainty whether you have or you haven't?

21 A. Correct.

22 Q. All right. Are you familiar with
23 the Guidance For Industry and FDA Pre-Market
24 and Post-Market Review Staff With Respect to
25 Incorporating Human Factors and Risk

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Page 104	Page 105
<p>1 W. VIGILANTE</p> <p>2 Management, the 2000 guidance?</p> <p>3 A. Am I familiar with their staff?</p> <p>4 Q. No. Are you -- the document is</p> <p>5 called Guidance For Industry and FDA</p> <p>6 Pre-Market and Post-Market Review Staff on</p> <p>7 Incorporating Human Factors and Risk</p> <p>8 Management. Are you familiar with that</p> <p>9 guidance document from 2000?</p> <p>10 A. I -- I'm familiar with the 2016.</p> <p>11 I don't think I've read the 2000.</p> <p>12 Q. Okay.</p> <p>13 A. Was it 2001? No, it was July 18,</p> <p>14 2000.</p> <p>15 Q. You haven't read that guidance?</p> <p>16 A. I have not.</p> <p>17 Q. Okay. The 2016 guidance, you're</p> <p>18 familiar with that?</p> <p>19 A. Yes.</p> <p>20 Q. Is this case the first time during</p> <p>21 which you've had occasion to read that 2016</p> <p>22 guidance?</p> <p>23 A. Yes.</p> <p>24 Q. Do you recognize that in that</p> <p>25 guidance FDA, first of all, does not require</p>	<p>1 W. VIGILANTE</p> <p>2 use of human factors?</p> <p>3 A. Yeah, I'm not sure that they</p> <p>4 require it. I think it's a -- a guideline</p> <p>5 recommendation.</p> <p>6 Q. Okay. And in that guideline</p> <p>7 recommendation, they -- they do not -- FDA</p> <p>8 does not specify the mode of human factors</p> <p>9 analysis that medical device manufacturers</p> <p>10 should incorporate; correct?</p> <p>11 A. One more time.</p> <p>12 Q. Sure. Let me see if I can</p> <p>13 rephrase it to be a little bit more clear.</p> <p>14 That guidance document, the 2016</p> <p>15 guidance document, suggests that when</p> <p>16 appropriate manufacturers should incorporate</p> <p>17 human factors into their design and labeling</p> <p>18 analysis; correct?</p> <p>19 A. It's my understanding it's a</p> <p>20 guidance, so I don't think it's a requirement.</p> <p>21 Q. Right. What I'm saying is: The</p> <p>22 FDA in that guidance document is suggesting to</p> <p>23 manufacturers that they consider incorporating</p> <p>24 human factors analyses when that's</p> <p>25 appropriate; correct?</p>
<p>1 W. VIGILANTE</p> <p>2 A. What they say is, and I'll read</p> <p>3 it, the guidance -- "This guidance recommends</p> <p>4 that manufacturers follow human factors or</p> <p>5 usability engineering processes during the</p> <p>6 development of new medical devices"; et</p> <p>7 cetera.</p> <p>8 So my understanding it's a -- the</p> <p>9 document is a guidance and that the FDA</p> <p>10 recommends it. It's not a requirement.</p> <p>11 Q. And in recommending the</p> <p>12 incorporation of human factors analyses, it</p> <p>13 does not specify what human factors processes</p> <p>14 or analyses the manufacturer is recommended to</p> <p>15 follow; correct?</p> <p>16 A. No, it does provide a list of</p> <p>17 different usability tools that the</p> <p>18 manufacturer should follow --</p> <p>19 Q. It does not specify --</p> <p>20 A. -- from -- from beginning --</p> <p>21 Q. -- which --</p> <p>22 A. -- to end.</p> <p>23 Q. -- one of those tools they should</p> <p>24 utilize if any.</p> <p>25 A. They do specify them. They're --</p>	<p>1 W. VIGILANTE</p> <p>2 they're -- they're laid out in the document</p> <p>3 of -- as to what human factors tools and</p> <p>4 evaluation should be done and at what parts of</p> <p>5 the design process they should be done.</p> <p>6 Q. Right. So it is your</p> <p>7 understanding that FDA is saying manufacturers</p> <p>8 should follow these processes?</p> <p>9 A. Yes, it's a recommended guidance.</p> <p>10 Q. All right. Issued in 2016?</p> <p>11 A. Issued in 2016. There was a -- my</p> <p>12 understanding is that the -- this 2016 version</p> <p>13 supersedes the 2000 version.</p> <p>14 Q. Which you have not read?</p> <p>15 A. I have not read that.</p> <p>16 Q. All right. Do you know what a</p> <p>17 device history file is?</p> <p>18 A. I do not know the technical</p> <p>19 definition of a device history file.</p> <p>20 Q. Do you know what a design history</p> <p>21 file is?</p> <p>22 A. Not as it's applied to medical</p> <p>23 devices.</p> <p>24 Q. Do you know what regulations</p> <p>25 govern the design history file?</p>

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1 W. VIGILANTE

2 A. I do not.

3 Q. I take it you've never maintained,
4 created, or reviewed a design history file?

5 A. I have. Not for medical products,
6 but for other consumer/commercial products.

7 Q. Right. But not for a medical
8 device as specified under the Federal
9 regulations?

10 A. Yes.

11 Q. Yes, you have; or, yes, that's
12 correct?

13 A. I'm sorry. I was agreeing with
14 you.

15 Q. Yeah. Okay. Have you read the
16 Federal statutes governing medical devices?

17 A. I have not read all the statutes
18 governing medical devices. The only one that
19 I read was the -- the notice in the Federal
20 register in -- from July 18, 2000.

21 Q. Which is what?

22 A. It is -- the volume -- it's
23 Volume 65, Number 138. The topic is Guidance
24 For Industry and FDA Reviewers on Medical
25 Device Use--Safety: Incorporating Human

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1 W. VIGILANTE

2 Factors Engineering Into Risk Management
3 Availability.

4 Q. Okay. And what you reviewed there
5 was the statement in the Code of Federal
6 Regulations; right?

7 A. Yes.

8 Q. All right. Have you read the
9 Federal regulations that govern the design,
10 labeling, and approval of medical devices?

11 A. I have not.

12 Q. Do you know what MDD 93/42/EEC
13 refers to?

14 A. I'm sorry. I'm not familiar with
15 it.

16 Q. Do you know what --

17 A. I'm sorry. I'm not familiar with
18 the statute number. Whether or not I've seen
19 the statute, I don't know.

20 Q. Okay. Do you know what EN 1441
21 Annex C refers to?

22 A. EN is a European standard
23 typically, but I have not reviewed that
24 standard at least for this case that I know
25 of.

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1 W. VIGILANTE

2 Q. Do you know what O.D.E. Guidance
3 is?

4 A. Yeah, not offhand.

5 Q. Okay. Do you -- are you familiar
6 with ISO 14971:2007?

7 A. What's the name of the standard?

8 Q. Medical Devices, Application of
9 Risk Management to Medical Devices.

10 A. I'm not familiar with it.

11 Q. Okay. Are you familiar with
12 IEC 60601-1-6:2010, Collateral Standard on
13 Usability?

14 A. I'm not familiar with it.

15 Q. Are you familiar with
16 IEC 62366:2007, Medical Devices, Application
17 of Usability Engineering in Medical Devices?

18 A. I don't believe I read it.

19 Q. Are you familiar with ANSI,
20 A-N-S-I, slash, Aami He752009, Human Factors
21 Engineering, Design of Medical Devices?

22 A. I don't recall if I read that or
23 not.

24 Q. Have you ever performed a formal
25 risk analysis?

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1 W. VIGILANTE

2 A. For a medical product or any
3 product?

4 Q. Well, let's start with a medical
5 product.

6 A. I have not for a medical product.

7 Q. Okay. Have you performed a formal
8 risk analysis for some other product?

9 A. For consumer and commercial
10 products I have.

11 Q. Okay. Consumer and commercial
12 products, you're distinguishing those from
13 medical devices; correct?

14 A. Sure.

15 Q. Okay. What process or methodology
16 have you used to perform a formal risk
17 analysis?

18 A. The risk analysis I've been
19 involved with were during my time at IBM in
20 product development. It was integrated into
21 the product development cycle and in --
22 different parties that were different members
23 of the Product Development Team fed into the
24 risk analysis. It was run and overseen by
25 the -- the Product Development Manager.

<p style="text-align: right;">Page 110</p> <p>1 W. VIGILANTE</p> <p>2 For my part, the product, both the</p> <p>3 concept and then once the concept was put into</p> <p>4 more physical form, was assessed for potential</p> <p>5 errors, potential hazards, potential problems.</p> <p>6 That was fed back into the risk assessment</p> <p>7 based upon the user's standpoint, the -- the</p> <p>8 product user's standpoint.</p> <p>9 The Engineering Teams, the Testing</p> <p>10 Teams all fed back into the -- the risk</p> <p>11 assessment based upon their disciplines and</p> <p>12 their types of testing and -- and data that</p> <p>13 they collect.</p> <p>14 Q. Those risk analyses that you were</p> <p>15 involved in were during your time at IBM I</p> <p>16 think you said?</p> <p>17 A. Yes.</p> <p>18 Q. So they involved computer</p> <p>19 software?</p> <p>20 A. I don't think I've done one for</p> <p>21 computer software. It was mostly for</p> <p>22 hardware.</p> <p>23 Q. Computer hardware?</p> <p>24 A. Yes.</p> <p>25 Q. Such as? Give me an example.</p>	<p style="text-align: right;">Page 111</p> <p>1 W. VIGILANTE</p> <p>2 A. I had a -- I've worked on the</p> <p>3 design development of laptops, desktops,</p> <p>4 monitors, input devices such as keyboards,</p> <p>5 mice, scanners, printers. I've worked on</p> <p>6 wireless devices, whether 802.11, Bluetooth.</p> <p>7 I worked on storage, tape storage, desktop</p> <p>8 tape storage, commercial storage, tape</p> <p>9 libraries, tape library pickers. Even worked</p> <p>10 on cameras at one point. So I think that's</p> <p>11 a -- kind of a good cross-reference of the</p> <p>12 different types of products I've worked on.</p> <p>13 Q. What was your role with respect to</p> <p>14 those -- well, actually, let me back up.</p> <p>15 How many such risk analyses did</p> <p>16 you participate in at your -- in your time at</p> <p>17 IBM?</p> <p>18 A. I don't have a number for you.</p> <p>19 Generally it would be done during the product</p> <p>20 design function. So if there were existing</p> <p>21 products that we're making cosmetic or minor</p> <p>22 changes to, we wouldn't go through a full risk</p> <p>23 analysis. It would only be products that</p> <p>24 we're developing either a new platform or a</p> <p>25 brand new product, like bringing a brand new</p>
<p style="text-align: right;">Page 112</p> <p>1 W. VIGILANTE</p> <p>2 product to market where it would be done. So</p> <p>3 I've worked on maybe over two dozen to three</p> <p>4 dozen products that fit that category.</p> <p>5 Q. Okay. And was your role -- let me</p> <p>6 see if I can come at it a different way.</p> <p>7 Were you looking at these products</p> <p>8 from the standpoint of primarily being</p> <p>9 concerned with repetitive stress injuries or</p> <p>10 what were you looking at?</p> <p>11 A. My role in the Product Development</p> <p>12 Team was the User Centered Design Team Lead.</p> <p>13 So I was responsible for the human factors,</p> <p>14 the ergonomics, the usability. So I had an</p> <p>15 assigned role on the teams, and my job was to</p> <p>16 represent the user. So I worked for the</p> <p>17 Design Team representing the user through all</p> <p>18 stages of -- of the design process from</p> <p>19 initial requirements gathering, the concept</p> <p>20 development, to initial prototypes, to the</p> <p>21 testing concepts, testing prototypes, getting</p> <p>22 physical products working, testing those with</p> <p>23 users and different usability techniques to</p> <p>24 validation and competitive benchmarking for</p> <p>25 the products; and then watching warranty and</p>	<p style="text-align: right;">Page 113</p> <p>1 W. VIGILANTE</p> <p>2 working with warranty and service to identify</p> <p>3 post-release problems that, you know, were not</p> <p>4 foreseen.</p> <p>5 So that's my role in the</p> <p>6 Development Teams.</p> <p>7 Q. Well, what I was trying to get at</p> <p>8 is with respect to those products at IBM, were</p> <p>9 you attempting to analyze the potential for</p> <p>10 injury?</p> <p>11 A. On some of the products potential</p> <p>12 for injury was a focus. Most -- all of the</p> <p>13 products usability and user error and</p> <p>14 potential damage to the machine was my focus.</p> <p>15 Q. What kind of injuries did you</p> <p>16 evaluate?</p> <p>17 A. For the smaller products, the</p> <p>18 biggest problem I had to worry about was sharp</p> <p>19 edges, and that's usually picked up by the</p> <p>20 manufacturing folks, but when I get into</p> <p>21 testing if it was -- if there was an issue, I</p> <p>22 would identify it, mark it, and have it get</p> <p>23 fixed.</p> <p>24 For the bigger products, like the</p> <p>25 tape library -- not the -- the tape libraries.</p>

<p style="text-align: right;">Page 114</p> <p>1 W. VIGILANTE</p> <p>2 The tape libraries with the pickers we had</p> <p>3 issues with the fact that we have large moving</p> <p>4 robotic arms on tracks that can crush and</p> <p>5 injure people. So there was issues related to</p> <p>6 crush hazards with the tape libraries; and the</p> <p>7 large tape storage or the large storage units</p> <p>8 our biggest issue was with the electric --</p> <p>9 electric shock and electrocution. So we had</p> <p>10 to identify potential is risks associated with</p> <p>11 the fact that they were high-voltage machines</p> <p>12 that both the typical user and the servicer</p> <p>13 and the installer had to access, and at</p> <p>14 different points in time at different parts of</p> <p>15 that access they may be exposed -- or the --</p> <p>16 the job was to prevent them from being exposed</p> <p>17 to the high-voltage areas of the machine.</p> <p>18 Q. Okay. Did -- in the -- in the</p> <p>19 risk analyses processes that you were involved</p> <p>20 in, was there a particular methodology of risk</p> <p>21 analysis that was utilized?</p> <p>22 A. Well, there was. Like for the --</p> <p>23 more of the engineering side the FMEAs were</p> <p>24 practiced, the failure modes effect analysis</p> <p>25 were done. Fault trees were done. My</p>	<p style="text-align: right;">Page 115</p> <p>1 W. VIGILANTE</p> <p>2 responsibility was doing it through usability</p> <p>3 testing, identifying issues that came up</p> <p>4 during task analysis, issues during the -- the</p> <p>5 assessment of the prototypes, issues that were</p> <p>6 identified during the -- the user testing.</p> <p>7 That -- that's where my focus was.</p> <p>8 Q. Okay. So -- and your focus, to</p> <p>9 the extent it was on usability testing, would</p> <p>10 involve both task analysis and then the</p> <p>11 usability side of it; correct?</p> <p>12 A. Well, there were multiple tools</p> <p>13 that I utilized working for IBM doing these,</p> <p>14 the product assessment; and it would be my</p> <p>15 responsibility as -- as opposed to that --</p> <p>16 that it be done and -- and done correctly as</p> <p>17 opposed to be the sole person doing it. But</p> <p>18 usability testing, focus groups, the cognitive</p> <p>19 walk-throughs, the -- the hallway testing, the</p> <p>20 task analysis, you know, these were all</p> <p>21 different tools that were -- that I utilized</p> <p>22 depending upon what pay -- what stage of the</p> <p>23 development process the product was in, what</p> <p>24 stage of the development process the</p> <p>25 assessment was done in, the time and the</p>
<p style="text-align: right;">Page 116</p> <p>1 W. VIGILANTE</p> <p>2 resources available.</p> <p>3 Q. Are you familiar with the phrase</p> <p>4 "use error"?</p> <p>5 A. I'm more familiar with the term</p> <p>6 "user error."</p> <p>7 Q. Okay. Are you able to define the</p> <p>8 phrase "use error"?</p> <p>9 A. You're going to have to give me a</p> <p>10 context.</p> <p>11 Q. In the medical device context are</p> <p>12 you familiar with that phrase?</p> <p>13 A. I'm not sure how they're defining</p> <p>14 it.</p> <p>15 Q. Okay. Let's talk about what you</p> <p>16 did to -- well, actually, let me -- before I</p> <p>17 get to that...</p> <p>18 (Exhibit Vigilante-5, multipage</p> <p>19 document entitled William Vigilante Human</p> <p>20 Factors ExpertVigilante Forensic, is marked</p> <p>21 for identification.)</p> <p>22 MR. SCHULTZ: Is that Number 5?</p> <p>23 COURT REPORTER: Yes.</p> <p>24 Q. Mr. Vigilante, the court reporter</p> <p>25 has handed you Exhibit Number 5 which -- well,</p>	<p style="text-align: right;">Page 117</p> <p>1 W. VIGILANTE</p> <p>2 do you recognize this document?</p> <p>3 A. Looks to be a poor printout of my</p> <p>4 home page and then looks like there's a</p> <p>5 printout of my about page.</p> <p>6 Q. Okay. Did you say "a poor</p> <p>7 printout"?</p> <p>8 A. Yeah, I mean this isn't what it</p> <p>9 looks like on my website, so it's a poor</p> <p>10 printout of the website.</p> <p>11 Q. Okay. Are you able to read it?</p> <p>12 A. There's a bunch of text that's</p> <p>13 obscured by the graphic.</p> <p>14 Q. That's on the front page, the</p> <p>15 landing page of the website; correct?</p> <p>16 A. The home page?</p> <p>17 Q. Right. The home page, landing</p> <p>18 page, right, where the language is obscured.</p> <p>19 A. Yeah, you're using a loose term.</p> <p>20 Landing page may not be the home page. It --</p> <p>21 so it depends on how you're using it, but this</p> <p>22 is my home page.</p> <p>23 Q. Right. And the term I used was I</p> <p>24 don't think loose. It was the home page's</p> <p>25 landing page.</p>

<p style="text-align: right;">Page 118</p> <p>1 W. VIGILANTE</p> <p>2 A. There's no such thing as a home</p> <p>3 page landing page. You can have a landing</p> <p>4 page and you can have a home page. They may</p> <p>5 be the same page. They may be different</p> <p>6 pages. So this is my home page.</p> <p>7 Q. Okay. Where you land if you are</p> <p>8 on the home page; right?</p> <p>9 A. No. The way they use the term</p> <p>10 "landing page" is that it's a page within the</p> <p>11 website that you're going to send the user to</p> <p>12 from another place. So, for example, if you</p> <p>13 have a pdf document related to, you know, I</p> <p>14 don't know, usability testing for medical</p> <p>15 products, and you have a link out to a</p> <p>16 website, that landing page from that document</p> <p>17 may not be the same as the home page for that</p> <p>18 website. So the landing page has a, you know,</p> <p>19 a specific use and meaning.</p> <p>20 Q. May I get you to turn to the</p> <p>21 second page of Exhibit 5.</p> <p>22 A. Sure.</p> <p>23 Q. This is the about page; right?</p> <p>24 A. I'm sorry. It's Page 3?</p> <p>25 Q. Page 3. I'm sorry.</p>	<p style="text-align: right;">Page 119</p> <p>1 W. VIGILANTE</p> <p>2 A. Yes.</p> <p>3 Q. The about page from your website;</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. Did you draft this content?</p> <p>7 A. Yes.</p> <p>8 Q. Is it true and complete?</p> <p>9 A. To the best of my knowledge.</p> <p>10 Q. Okay.</p> <p>11 MR. SCHULTZ: Can you mark this one?</p> <p>12 (Exhibit Vigilante-6, multipage</p> <p>13 document entitled Human Factors Expert</p> <p>14 Services Vigilante Forensic, is marked for</p> <p>15 identification.)</p> <p>16 A. I've seen a couple typos.</p> <p>17 Q. Mr. Vigilante, the court reporter</p> <p>18 has handed you Exhibit Number 6. Do you</p> <p>19 recognize Exhibit Number 6 as a true and</p> <p>20 correct copy of the portion of your website</p> <p>21 indicating "Practice Areas"?</p> <p>22 A. Vigilante-6 is a poor copy of my</p> <p>23 services page.</p> <p>24 Q. Okay. Forgive me. Your services</p> <p>25 page.</p>
<p style="text-align: right;">Page 120</p> <p>1 W. VIGILANTE</p> <p>2 Does it -- is that an exhibit --</p> <p>3 or is that content that you drafted?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. Is it true and accurate?</p> <p>6 A. Well, as I noticed on the last</p> <p>7 about page, there's some grammatical errors,</p> <p>8 so I don't know how accurate it is, but for</p> <p>9 the most part, it's meant to be accurate.</p> <p>10 Q. Right. Grammatical errors or</p> <p>11 typos aside, it's accurate?</p> <p>12 A. It was my intent, yes.</p> <p>13 Q. Yeah.</p> <p>14 (Exhibit Vigilante-7, multipage</p> <p>15 document entitled Bill Vigilante LinkedIn,</p> <p>16 is marked for identification.)</p> <p>17 Q. Do you recognize Vigilante Exhibit</p> <p>18 Number 7?</p> <p>19 A. It looks like a printout from my</p> <p>20 LinkedIn page.</p> <p>21 Q. And did you draft that content?</p> <p>22 A. The content under "Summary" and</p> <p>23 "Experience," yes.</p> <p>24 Q. Okay.</p> <p>25 A. And the -- yeah, yes.</p>	<p style="text-align: right;">Page 121</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay. Did you -- is it true and</p> <p>3 accurate?</p> <p>4 A. To the best of -- well, I can't</p> <p>5 say to the best of my ability, but that was my</p> <p>6 intent.</p> <p>7 (Exhibit Vigilante-8, multipage</p> <p>8 document entitled William J. Vigilante,</p> <p>9 PhD, CPE - SEAK, Inc. Expert Witness</p> <p>10 Directory, is marked for identification.)</p> <p>11 Q. Do you recognize Vigilante-8?</p> <p>12 A. I know what it is. I don't know</p> <p>13 that I've ever physically went to the website</p> <p>14 and looked myself up.</p> <p>15 Q. It's a printout of the information</p> <p>16 that you provided to an expert witness service</p> <p>17 called SEAK; correct?</p> <p>18 A. Yes.</p> <p>19 Q. And the information that is</p> <p>20 included in that expert witness profile is</p> <p>21 information you provided, is it not?</p> <p>22 A. That is -- that would be my</p> <p>23 belief, yes.</p> <p>24 Q. And can you tell or do you recall</p> <p>25 when you provided this information to the SEAK</p>

<p style="text-align: right;">Page 122</p> <p>1 W. VIGILANTE</p> <p>2 Expert Witness Directory?</p> <p>3 A. I don't know that I have a</p> <p>4 specific date, but I can tell you it's</p> <p>5 sometime between October 1st, 2015 and today.</p> <p>6 Q. Because it's after you formed</p> <p>7 Vigilante Consulting; correct?</p> <p>8 A. That's correct.</p> <p>9 Q. All right. And in the front page</p> <p>10 of this expert witness directory it says,</p> <p>11 "Number Of Times Deposed/Testified in the Last</p> <p>12 4 Years." You've written "50 plus."</p> <p>13 Do you see that?</p> <p>14 A. Yes.</p> <p>15 Well, wait, wait, wait. It -- so</p> <p>16 one of the things I want to clarify is that</p> <p>17 for the SEAK Expert Witness Directory, which</p> <p>18 is a website page from, I had to go -- I don't</p> <p>19 remember if it was online or they sent me a</p> <p>20 paper application, and they were -- like under</p> <p>21 "General Specialties" I didn't write myself</p> <p>22 "Human factors, warnings and labels." Like</p> <p>23 there were selections I had to choose from.</p> <p>24 Like I had to select, you know, one or two</p> <p>25 from the -- from the below list; and the same</p>	<p style="text-align: right;">Page 123</p> <p>1 W. VIGILANTE</p> <p>2 thing with "Specialty Focus." I think</p> <p>3 "Education" was a free form. "Years in</p> <p>4 Practice" was free form. And I don't remember</p> <p>5 "Number Of Times Deposed/Testified in the Last</p> <p>6 4 Years" if there was a selection or if that</p> <p>7 was free form. So I -- I can't testify that</p> <p>8 that's what I wrote. That might have been my</p> <p>9 only selection.</p> <p>10 Q. I gotcha. But if it was a</p> <p>11 selection, you selected more than 50 times;</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. All right. And that's true and</p> <p>15 accurate when you made that selection; right?</p> <p>16 A. Yes.</p> <p>17 Q. And the "Additional Information"</p> <p>18 that's provided on Pages 2 and 3 of this</p> <p>19 particular exhibit, that's free-form</p> <p>20 information? In other words, you wrote it;</p> <p>21 right?</p> <p>22 A. I'm going to -- the safest way to</p> <p>23 answer that is to say that I wrote the</p> <p>24 information and put it into the system. I</p> <p>25 don't know if -- if SEAK went in and edited it</p>
<p style="text-align: right;">Page 124</p> <p>1 W. VIGILANTE</p> <p>2 for -- to shorten it because it couldn't be so</p> <p>3 long. That's possible without going back to</p> <p>4 see what I submitted. I don't recall. But I</p> <p>5 would have provided them the initial content,</p> <p>6 and if they edited it, they edited it. If</p> <p>7 not, then it's exactly what I provided.</p> <p>8 Q. You're not aware of any edits that</p> <p>9 they made, are you?</p> <p>10 A. Like I said, I don't know if they</p> <p>11 do or not. I -- I don't -- I don't recall.</p> <p>12 Q. Well, why don't you take a moment</p> <p>13 to read the "Additional Information" and tell</p> <p>14 me if you view it to be edited or incomplete</p> <p>15 or inaccurate.</p> <p>16 A. I can read it and give you an</p> <p>17 assessment of the third request, but the first</p> <p>18 two I would have to go back and see what I</p> <p>19 initially submitted.</p> <p>20 Q. Well, why don't you read it and</p> <p>21 I'll ask you some follow-up questions.</p> <p>22 A. Sure. Okay.</p> <p>23 (Reviewing document.)</p> <p>24 Okay.</p> <p>25 Q. You've had an opportunity to read</p>	<p style="text-align: right;">Page 125</p> <p>1 W. VIGILANTE</p> <p>2 the "Additional Information" on Exhibit 8?</p> <p>3 A. Yes.</p> <p>4 Q. Is it truthful?</p> <p>5 A. Yes.</p> <p>6 Q. Is it incomplete?</p> <p>7 A. I'm sorry? Is it incomplete?</p> <p>8 Q. Yes, sir.</p> <p>9 A. Incomplete of what?</p> <p>10 Q. Incomplete for what you're</p> <p>11 describing in there.</p> <p>12 Well, what are you attempting to</p> <p>13 describe in the "Additional Information"?</p> <p>14 A. Just the general background of</p> <p>15 the -- my experiences and the type of work I</p> <p>16 do. I mean, it -- for, you know, what it's</p> <p>17 meant to be, it seems to be complete. If it</p> <p>18 was meant for something else, it might not be</p> <p>19 complete.</p> <p>20 Q. But for what it was meant to be,</p> <p>21 it's a complete description?</p> <p>22 A. For what it's supposed to be, it</p> <p>23 seems to be right.</p> <p>24 Q. And what's it supposed to be?</p> <p>25 A. The additional information</p>

<p style="text-align: right;">Page 126</p> <p>1 W. VIGILANTE</p> <p>2 describing my background and the type of work</p> <p>3 I do that would fit in the field and area that</p> <p>4 was offered.</p> <p>5 Q. What field and area was it offered</p> <p>6 in?</p> <p>7 A. It's a website. There's --</p> <p>8 there's a form. They're typically limited</p> <p>9 for -- for text and characters. So if it was</p> <p>10 limited for text and characters that's where I</p> <p>11 had to fit it into; and like I said, if I had</p> <p>12 given them information and they needed to cut</p> <p>13 it down, they may have edited it. I just</p> <p>14 don't know at this point.</p> <p>15 Q. Are there significant areas of</p> <p>16 your qualifications as an expert in the fields</p> <p>17 of human factors and ergonomics that are</p> <p>18 missing from that description?</p> <p>19 A. Well, I have a whole CV that's --</p> <p>20 that's, what, ten pages long and this is just</p> <p>21 one form on a website. So, yeah, I mean, I --</p> <p>22 I couldn't fit everything in there.</p> <p>23 Q. Okay. So your -- your CV is the</p> <p>24 most complete statement of your experience;</p> <p>25 correct?</p>	<p style="text-align: right;">Page 127</p> <p>1 W. VIGILANTE</p> <p>2 A. Yes.</p> <p>3 MR. SCHULTZ: All right. Why don't</p> <p>4 you mark that.</p> <p>5 (Exhibit Vigilante-9, multipage</p> <p>6 document entitled William J. Vigilante,</p> <p>7 Jr.: Real Estate - Human Factors::</p> <p>8 JurisPro Expert Witness Directory, is</p> <p>9 marked for identification.)</p> <p>10 Q. Do you recognize Vigilante-9?</p> <p>11 A. Yes.</p> <p>12 Q. What is it?</p> <p>13 A. It's my listing in the JurisPro</p> <p>14 Expert Witness Directory.</p> <p>15 Q. That's also something that you</p> <p>16 created, correct, or inputted if you will?</p> <p>17 A. Yes, I -- I -- there were forms</p> <p>18 that I input into.</p> <p>19 Q. Okay. And much of this document</p> <p>20 is in the form of questions and answers;</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 Q. And the questions were questions</p> <p>24 provided by JurisPro Expert Witness Directory</p> <p>25 and the answers are what you typed in;</p>
<p style="text-align: right;">Page 128</p> <p>1 W. VIGILANTE</p> <p>2 correct?</p> <p>3 A. Yes.</p> <p>4 Yeah, so it looks like some of</p> <p>5 this information is outdated.</p> <p>6 Q. What information is outdated?</p> <p>7 A. Without going through all of it,</p> <p>8 for example, it says, "When was the last time</p> <p>9 you had your deposition taken," and I put</p> <p>10 October 2015. Obviously that's incorrect. I</p> <p>11 think this is the information that I had at</p> <p>12 the time I filled the form out in probably</p> <p>13 October of 2015. My rate has changed too. So</p> <p>14 I know that's different. And then how many</p> <p>15 years I've worked in the legal industry as</p> <p>16 a -- as an expert, that should be 14 plus, not</p> <p>17 13 plus because it's the next year.</p> <p>18 Q. So in other words --</p> <p>19 A. I've got a -- "How many occasions</p> <p>20 have you been qualified by a court to give</p> <p>21 expert testimony?" Well, I guess that's</p> <p>22 right, 35 plus, that still fits.</p> <p>23 Number -- "On how many occasions</p> <p>24 you have testified as an expert in court or</p> <p>25 before an arbitrator" the answer is 32, it's</p>	<p style="text-align: right;">Page 129</p> <p>1 W. VIGILANTE</p> <p>2 actually 36 at this point.</p> <p>3 Everything else seems to be</p> <p>4 reasonably accurate.</p> <p>5 Q. Okay. Have you worked with</p> <p>6 Mr. Haverty on litigation matters before?</p> <p>7 A. I have not.</p> <p>8 Q. Have you worked with members of</p> <p>9 his firm, Williams Cuker & Berezofsky, before</p> <p>10 this case?</p> <p>11 A. It's possible, but I don't know.</p> <p>12 The name of the firm is not familiar to me.</p> <p>13 Q. Is everything that you reviewed in</p> <p>14 arriving at your opinions listed in your</p> <p>15 report -- or reports?</p> <p>16 A. Everything I plan on relying upon,</p> <p>17 yes.</p> <p>18 Q. Did you review materials that</p> <p>19 you're not relying on?</p> <p>20 A. It's possible that I looked up</p> <p>21 websites. Like when I pulled down the -- the</p> <p>22 FDA CFR document, I would have done a web</p> <p>23 search on human factors in design of medical</p> <p>24 devices, and I can't say that there was other</p> <p>25 websites that I looked at that I didn't rely</p>

<p style="text-align: right;">Page 130</p> <p>1 W. VIGILANTE</p> <p>2 upon or -- download and rely upon. So</p> <p>3 certainly there's potential I looked at other</p> <p>4 information, but the things I'm relying upon</p> <p>5 are listed in my report or provided with me</p> <p>6 here today.</p> <p>7 Q. Okay. Were you provided</p> <p>8 information or documents that you did not rely</p> <p>9 upon?</p> <p>10 A. Certainly in all of the documents</p> <p>11 I got, some were more relevant to what I was</p> <p>12 doing than others. So I think that's the best</p> <p>13 way to put it.</p> <p>14 Q. Are any of the documents that you</p> <p>15 were provided not listed in your report?</p> <p>16 A. Reports. If it's reports --</p> <p>17 Q. Reports. Sorry.</p> <p>18 A. Yes, I did receive the deposition</p> <p>19 of Dr. Klimowicz, and that's not listed in any</p> <p>20 of my reports.</p> <p>21 Q. Okay. Other than Mr. Klimowicz's</p> <p>22 report, anything that's not listed in your</p> <p>23 reports?</p> <p>24 A. The only thing that's not listed</p> <p>25 in the report was the 2006 FDA document</p>	<p style="text-align: right;">Page 131</p> <p>1 W. VIGILANTE</p> <p>2 "Applying Human Factors and Usability</p> <p>3 Engineering to Medical Devices, Guidance For</p> <p>4 Industry and Food and Drug Administration</p> <p>5 Staff."</p> <p>6 Q. Did you say 2006 or 2016?</p> <p>7 A. 2016.</p> <p>8 Q. Okay. All right. Now --</p> <p>9 A. I may have said 2006. If I did, I</p> <p>10 apologize.</p> <p>11 Q. You -- you meant 2016 if you did.</p> <p>12 All right. Did you conduct any</p> <p>13 interviews as part of your opinion</p> <p>14 formulation?</p> <p>15 A. The only thing that I would --</p> <p>16 fall into that category is my discussion</p> <p>17 with -- telephone discussion with</p> <p>18 Dr. Kilowicz --</p> <p>19 Q. Okay.</p> <p>20 A. -- Klimowicz.</p> <p>21 Q. When did --</p> <p>22 A. Sorry.</p> <p>23 Q. -- that occur?</p> <p>24 A. April 13, 2016.</p> <p>25 Q. And what was your purpose for</p>
<p style="text-align: right;">Page 132</p> <p>1 W. VIGILANTE</p> <p>2 speaking with Mr. Klimowicz?</p> <p>3 A. I think that was the beginning of</p> <p>4 my report writing. So I wanted to go over</p> <p>5 with Dr. Klimowicz his opinions, his findings,</p> <p>6 and make sure that I have a -- a correct</p> <p>7 understanding of -- of the things I was</p> <p>8 talking about.</p> <p>9 Q. Okay. We'll come back to that.</p> <p>10 But in general, am I correct in</p> <p>11 understanding that you were talking to</p> <p>12 Dr. Klimowicz or Mr. Klimowicz so that you</p> <p>13 could understand what he was opining was the</p> <p>14 failure mechanism at issue in this case; is</p> <p>15 that a fair summary?</p> <p>16 A. Yeah, so I have notes from the</p> <p>17 teleconference and I can tell you the things</p> <p>18 we talked about, and certainly one of the</p> <p>19 things that I wanted to get from the dep -- or</p> <p>20 from the teleconference was what mis -- or</p> <p>21 Dr. Klimowicz's findings, opinions were --</p> <p>22 were going to be, you know, what -- what was</p> <p>23 his findings through his investigation.</p> <p>24 Q. Okay. And you -- you have notes</p> <p>25 of that telephone conference?</p>	<p style="text-align: right;">Page 133</p> <p>1 W. VIGILANTE</p> <p>2 A. Yes.</p> <p>3 Q. Was anybody else on the call?</p> <p>4 A. Mr. Haverty.</p> <p>5 Q. Okay. Were you relying upon</p> <p>6 Mr. Klimowicz's facts or opinions in drafting</p> <p>7 your report?</p> <p>8 A. As the subject matter expert I was</p> <p>9 relying upon him in part, yes.</p> <p>10 Q. Okay. Did you -- did</p> <p>11 Mr. Klimowicz tell you anything of a factual</p> <p>12 nature that you did not include in your</p> <p>13 reports?</p> <p>14 A. I don't know.</p> <p>15 Q. That's something that would be</p> <p>16 discernable from your notes perhaps?</p> <p>17 A. Yes.</p> <p>18 Q. Tell me what your -- just, in</p> <p>19 general, tell me your process, the process you</p> <p>20 went through to formulate your opinions in</p> <p>21 this case.</p> <p>22 A. Yeah, so I rely upon the</p> <p>23 scientific method when I do a investigation,</p> <p>24 particularly for assessment of -- of warnings</p> <p>25 for a product. I start with a -- typically it</p>

<p style="text-align: right;">Page 134</p> <p>1 W. VIGILANTE</p> <p>2 starts with a call from a client and I get</p> <p>3 general question areas that I'm asked to -- to</p> <p>4 look at.</p> <p>5 I start doing some research,</p> <p>6 whether it's, you know, online research</p> <p>7 looking at the product, looking at maybe</p> <p>8 information that's out there related to the</p> <p>9 product, looking at things that are related to</p> <p>10 the product.</p> <p>11 Then I start drafting hypotheses</p> <p>12 based upon my review of the initial -- my</p> <p>13 initial review of the information. I then</p> <p>14 continue with the -- the -- and it could be,</p> <p>15 depending upon the time frame, it could be</p> <p>16 condensed into a few weeks, it could be</p> <p>17 dragged out over a few months. But as the</p> <p>18 discovery information starts coming in, I</p> <p>19 start gathering the facts of what happened,</p> <p>20 how it happened, who was involved, when it</p> <p>21 happened, and so forth.</p> <p>22 So I look at what was done from</p> <p>23 the manufacturer's standpoint, when it was</p> <p>24 done, how it was done, what they did with</p> <p>25 warnings, with -- what -- what was the end</p>	<p style="text-align: right;">Page 135</p> <p>1 W. VIGILANTE</p> <p>2 result, who was involved, what type of</p> <p>3 assessments we're doing. Same thing with the</p> <p>4 risk assessment and identifying foreseeable</p> <p>5 hazards associated with the product.</p> <p>6 I then -- once I'm done with the</p> <p>7 discovery material, I look at what is the</p> <p>8 standard of care for product developers,</p> <p>9 warning -- warning designers and developers</p> <p>10 and look to see whether or not the -- in this</p> <p>11 case whether or not the manufacturer --</p> <p>12 manufacturers met the standard of care. And</p> <p>13 then I also look at whether or not their --</p> <p>14 their warnings, instructions, in this case the</p> <p>15 IFUs, met the standard of care for the</p> <p>16 presentation of instructional and warnings</p> <p>17 information.</p> <p>18 And then I come to my conclusions</p> <p>19 based upon my assessment of whether or not</p> <p>20 they met the standard of care; and then I</p> <p>21 formalize and memorialize my opinions in my</p> <p>22 reports.</p> <p>23 Q. Okay.</p> <p>24 A. If it's a -- that's what I did for</p> <p>25 this case. Some -- some courts, they don't</p>
<p style="text-align: right;">Page 136</p> <p>1 W. VIGILANTE</p> <p>2 require reports, so it may be done in an</p> <p>3 affidavit or disclosure, some other method,</p> <p>4 but for this case it's memorialized in a</p> <p>5 report.</p> <p>6 Q. Right. You said at the beginning</p> <p>7 of this that you follow the scientific method.</p> <p>8 Would you define for me what you mean by "the</p> <p>9 scientific method"?</p> <p>10 A. Sure. You know, the scientific</p> <p>11 method you start with questions. You develop</p> <p>12 hypotheses from your initial research. You</p> <p>13 collect data. You put together a way to</p> <p>14 collect that data, a way to test that data.</p> <p>15 You do the -- you do the -- the assessment,</p> <p>16 the testing of the data you collected; and</p> <p>17 then you analyze that data and you determine</p> <p>18 whether or not your hypotheses were supported</p> <p>19 or not. And then, of course, part of it is --</p> <p>20 is memorializing it.</p> <p>21 Q. Did you, as part of your opinion</p> <p>22 formulation process in this case, did you ask</p> <p>23 for or review the design history file for the</p> <p>24 P-cap or what others refer to as the</p> <p>25 proprietary connector?</p>	<p style="text-align: right;">Page 137</p> <p>1 W. VIGILANTE</p> <p>2 A. I did not ask for it.</p> <p>3 Q. Did you receive it?</p> <p>4 A. I don't -- I don't know if it was</p> <p>5 in the discovery material that I have. That's</p> <p>6 the -- I don't know if it was received in the</p> <p>7 discovery material.</p> <p>8 Q. Okay. Do you -- were there --</p> <p>9 were any fact provided to you by any person</p> <p>10 that you relied upon in formulating your</p> <p>11 opinion?</p> <p>12 In other words -- and let -- let</p> <p>13 me just be clear. I'm asking you for factual</p> <p>14 information as distinct for -- from</p> <p>15 conversations that you may have had with, for</p> <p>16 example, Mr. Haverty about matters of a</p> <p>17 non-factual nature.</p> <p>18 A. Yeah, so all the facts that I used</p> <p>19 to -- to support my analysis and opinions are</p> <p>20 laid out in the report; and they're identified</p> <p>21 specifically by the party and if it's a</p> <p>22 deposition, the page number on which the party</p> <p>23 testified to that particular fact.</p> <p>24 Q. Okay. Let -- let me rephrase the</p> <p>25 question a little bit.</p>

<p style="text-align: right;">Page 138</p> <p>1 W. VIGILANTE</p> <p>2 What I was trying to get at was</p> <p>3 whether you were provided facts by any person</p> <p>4 where the facts were not either contained in</p> <p>5 deposition testimony or in documents produced</p> <p>6 in discovery.</p> <p>7 A. I don't know how to answer that</p> <p>8 'cause I'm not really sure what you're asking</p> <p>9 about.</p> <p>10 So the case-specific facts I</p> <p>11 received through the discovery documents and</p> <p>12 my conversation with Dr. Klimowicz. I didn't</p> <p>13 have another source for case-specific facts.</p> <p>14 Q. Yeah. I can ask it a different</p> <p>15 way. I -- I -- I think I know your answer,</p> <p>16 but I just need to be clear.</p> <p>17 Did Mr. Haverty or Mr. Klimowicz</p> <p>18 or any other person verbally provide you</p> <p>19 factual information that you relied upon those</p> <p>20 statements in formulating your opinions?</p> <p>21 A. Not from Mr. Haverty, but from</p> <p>22 Dr. Klimowicz. Again, we had a teleconference</p> <p>23 to go over his opinions and findings because</p> <p>24 he was -- you know, he's reporting -- he's</p> <p>25 writing his report while I'm writing my</p>	<p style="text-align: right;">Page 139</p> <p>1 W. VIGILANTE</p> <p>2 report. He couldn't very well give me it at</p> <p>3 start of my report writing, so I would have</p> <p>4 relied upon that conversation in part for some</p> <p>5 of my work --</p> <p>6 Q. Okay.</p> <p>7 A. -- understanding different aspects</p> <p>8 of what he was doing and so forth.</p> <p>9 Q. Right. And -- and those -- that</p> <p>10 information revolved around the alleged</p> <p>11 failure mechanism of the temporary blocked</p> <p>12 vent; correct?</p> <p>13 A. Oh, I've got a whole sheet of</p> <p>14 notes, so -- as to what the conversations were</p> <p>15 about. So part of the notes are certainly the</p> <p>16 defects that he identified with the -- with</p> <p>17 the product, with the P-cap and the -- the</p> <p>18 Paradigm Reservoir and the infusion set.</p> <p>19 We talked about the -- the Lot 8</p> <p>20 problems. We talked about the -- how the</p> <p>21 infusion device goes through the 501(k) [sic]</p> <p>22 device process. So certainly I'm not an</p> <p>23 expert in that process. I would leave</p> <p>24 testimony to that process to Dr. Klimowicz.</p> <p>25 You know, we -- we talked about</p>
<p style="text-align: right;">Page 140</p> <p>1 W. VIGILANTE</p> <p>2 how the different components of the system and</p> <p>3 what are -- where -- where they fall within</p> <p>4 the regulatory process.</p> <p>5 You know, we went through the</p> <p>6 infusion set. I had some questions about what</p> <p>7 the -- I have the -- I had a -- a sample of</p> <p>8 the infusion set and the reservoir. I just</p> <p>9 wanted to make sure I was correct in my</p> <p>10 understanding of what was included in -- in</p> <p>11 each part of it.</p> <p>12 We talked about how they were sold</p> <p>13 and what came with them. We talked about</p> <p>14 the -- the pump being an approved medical</p> <p>15 device and some of the submission process for</p> <p>16 that. You know, we talked about the fact that</p> <p>17 the infusion set and the reservoir were not</p> <p>18 considered a medical device like the pump,</p> <p>19 that there was no thorough assessment and</p> <p>20 approval of the product and instructions by</p> <p>21 the FDA.</p> <p>22 We kind of went over the history a</p> <p>23 little bit of -- of -- of the Paradigm -- of</p> <p>24 the Paradigm pump and the initial -- one of</p> <p>25 the initial requirements that it be</p>	<p style="text-align: right;">Page 141</p> <p>1 W. VIGILANTE</p> <p>2 waterproof, and how that requirement</p> <p>3 eventually got dropped, but they didn't change</p> <p>4 the design of the vent cap -- of the vents in</p> <p>5 the cap.</p> <p>6 You know, Dr. Klimowicz described</p> <p>7 to me that it only happens during priming, it</p> <p>8 doesn't happen if -- if you do a bolus later</p> <p>9 on. He talked to me a little bit about the</p> <p>10 glucose monitor sensor and how it transmits</p> <p>11 data. He went over the manual prime procedure</p> <p>12 a little bit. He, you know, went over the</p> <p>13 fact that there was no evidence that the</p> <p>14 infusion tube was connected to the cannula</p> <p>15 before she primed the tube.</p> <p>16 Yeah, we talked about the fact and</p> <p>17 re -- reiterated the fact that you can't have</p> <p>18 any -- any liquids or contaminants on the</p> <p>19 reservoir before attaching the P-cap and that</p> <p>20 it should be wiped down in -- with an alcohol</p> <p>21 swab; and that the -- we discussed that the</p> <p>22 warning should have included -- the warnings</p> <p>23 for -- the IFU should have included a warning</p> <p>24 to that effect.</p> <p>25 Q. A warning to what effect?</p>

<p style="text-align: right;">Page 142</p> <p>1 W. VIGILANTE</p> <p>2 A. That it needs to be -- do not</p> <p>3 allow liquids, et cetera, from contacting the</p> <p>4 top of the reservoir, to wipe it down, et</p> <p>5 cetera, and that can cause problems if you</p> <p>6 don't, or if there is, and you don't.</p> <p>7 And we talked about the -- the</p> <p>8 need to refill or change the reservoir and set</p> <p>9 every three days and that -- you know, we also</p> <p>10 talked about that it's foreseeable you can</p> <p>11 miss the step of turning the vial back over.</p> <p>12 Even if you know it or are taught it, you may</p> <p>13 have forgotten, you may have misunderstand it,</p> <p>14 distracted, hurrying. So there's a -- a -- a</p> <p>15 list of different things that can occur that</p> <p>16 just makes it a bad -- a bad design in -- in</p> <p>17 making that requirement for the litany of</p> <p>18 reasons why people inadvertently do things</p> <p>19 because they're, in fact, human and they're</p> <p>20 expressing human tendencies such as</p> <p>21 inattention, distraction, forgetting,</p> <p>22 hurrying, so forth.</p> <p>23 Q. And those facts that you've just</p> <p>24 relayed here or related here came from you --</p> <p>25 came to you from Mr. Klimowicz; right?</p>	<p style="text-align: right;">Page 143</p> <p>1 W. VIGILANTE</p> <p>2 A. No, I don't know that I would</p> <p>3 describe them as facts. I would describe them</p> <p>4 as discussion. Some of them are facts and</p> <p>5 some of it's discussion. Some of it's</p> <p>6 Dr. Klimowicz explaining things to me better,</p> <p>7 reinforcing what I've already known or me</p> <p>8 talking with him about what my take on the</p> <p>9 issue is.</p> <p>10 Q. And you incorporated some of that</p> <p>11 information into your report; right?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. You said a moment -- well,</p> <p>14 first of all, you have a reservoir and an</p> <p>15 infusion set you were provided; is that</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. Where did you get that?</p> <p>19 A. Mr. Haverty's office.</p> <p>20 Q. Okay. Do you know where</p> <p>21 Mr. Haverty obtained them or do you have an</p> <p>22 understanding?</p> <p>23 A. Yeah, I'm not sure if he obtained</p> <p>24 them upon initiation of his involvement in</p> <p>25 this suit or if these were actually left over</p>
<p style="text-align: right;">Page 144</p> <p>1 W. VIGILANTE</p> <p>2 from what the plaintiff and her mother</p> <p>3 recovered after the incident.</p> <p>4 Q. Okay. You said earlier when you</p> <p>5 were describing or reading from your notes of</p> <p>6 your conversation with Mr. Klimowicz that the</p> <p>7 infusion set and reservoir were not a medical</p> <p>8 device the way the pump was. Do you recall</p> <p>9 saying that?</p> <p>10 A. I don't know if I used those words</p> <p>11 exactly, but I recall that topic coming up</p> <p>12 in --</p> <p>13 Q. What --</p> <p>14 A. -- the conversation.</p> <p>15 Q. What do you mean by that?</p> <p>16 A. It's my understanding that the --</p> <p>17 the pump has to go -- is a medical device</p> <p>18 that's approved by the FDA, that the IF -- IFU</p> <p>19 is approved by the FDA and that it goes</p> <p>20 through a different regulatory process than</p> <p>21 the infusion set and the reservoir. So that</p> <p>22 there's a -- there's a different process and</p> <p>23 different regulations that apply to the -- the</p> <p>24 two sets of products.</p> <p>25 Q. As to how those review processes</p>	<p style="text-align: right;">Page 145</p> <p>1 W. VIGILANTE</p> <p>2 work, you're not familiar with them; correct?</p> <p>3 A. Yeah, that's not my area of</p> <p>4 expertise.</p> <p>5 Q. Okay. In fact, you said a moment</p> <p>6 ago that one of them was the 501(k) process.</p> <p>7 You meant 510(k); right?</p> <p>8 A. If I said 501, I meant 510(k)</p> <p>9 'cause I've got 510(k) written in my notes.</p> <p>10 Q. Okay. And the 510(k) process, is</p> <p>11 it your understanding that that does not</p> <p>12 involve -- I think you used the phrase that</p> <p>13 the FDA does not fully consider the device in</p> <p>14 that process?</p> <p>15 A. It's my understanding that the IFU</p> <p>16 for the pump is considered a label and it's</p> <p>17 submitted with the application for approval,</p> <p>18 but it's not the case that the FDA reviews and</p> <p>19 signs off on the IFU for the reservoir and the</p> <p>20 infusion set.</p> <p>21 Q. Okay. And that's information or</p> <p>22 an understanding provided to you by</p> <p>23 Mr. Klimowicz?</p> <p>24 A. That would have been one of the</p> <p>25 topics that Dr. Klimowicz went over with me.</p>

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2 Q. Okay. Are you aware that by
3 clearing a medical device through the 510(k)
4 process, the FDA has determined that to its
5 satisfaction the device is reasonably safe and
6 effective for use by the public?

7 MR. HAVERTY: Objection. If you
8 know. Do you know anything about the
9 510(k) process?

10 A. Yeah, I would leave that, those
11 questions to Dr. Klimowicz.

12 Q. Well, if you leave those questions
13 to Dr. Klimowicz and you can't say that the
14 510(k) process results in an FDA determination
15 of reasonable safety and effectiveness, why
16 are you then relying on the portion of
17 Mr. Klimowicz's discussion with you that says
18 the FDA hasn't fully considered the product?

19 MR. HAVERTY: Well, Dave, first of
20 all --

21 Q. I mean --

22 MR. HAVERTY: -- this is a legal
23 issue as you well know. He is not familiar
24 with the 510(k) process. He's just
25 reciting what Mr. Klimowicz told him.

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2 Q. Go ahead.

3 A. I never testified that I was
4 relying upon that for my opinions. It was
5 something that we talked about in the
6 teleconference. Any questions that relate to
7 the process, 5 -- 510(k) process I will leave
8 to Dr. Klimowicz, but, you know, knowledge of
9 that process wasn't necessary for my analysis.

10 Q. Okay. You're not suggesting that
11 somehow the FDA didn't fully and appropriately
12 consider the safety and efficacy of the
13 infusion set and reservoir when it cleared
14 those devices, are you?

15 MR. HAVERTY: Wait. Whoa.
16 Objection.

17 Dave, you know that's not the
18 standard. The 510(k) is a different legal
19 standard and you're asking him the
20 question. It -- it's too murky and it's
21 beyond his expertise anyway.

22 MR. SCHULTZ: Well, he can say, no,
23 he's not if that's the answer.

24 MR. HAVERTY: Or he can say he
25 doesn't know one way or the other.

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2 A. Yeah, my -- my answer is --

3 MR. SCHULTZ: Yeah, we should
4 probably --

5 THE WITNESS: I'm sorry.

6 MR. SCHULTZ: -- let him testify.

7 Why don't you read my question back?

8 (The following portion of the record
9 is read by the court reporter:

10 QUESTION: Okay. You're not
11 suggesting that somehow the FDA didn't
12 fully and appropriately consider the safety
13 and efficacy of the infusion set and
14 reservoir when it cleared those devices,
15 are you?")

16 MR. HAVERTY: Note my objection.

17 A. Yeah, so my answer is I -- I don't
18 know what the process is, so I don't know what
19 the FDA did with -- with respect to the
20 process, so I don't know. Again, I leave
21 questions like that to Dr. Klimowicz.

22 The other thing I want to just
23 point real quick out, you know, I don't care
24 on the record, off the record, but I need to
25 take a lunch break. So if you got another

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2 question or two, I'm happy to oblige, but I
3 need to take a lunch break.

4 Q. We can take a break.

5 A. Okay. Thank you.

6 THE VIDEOGRAPHER: We are now going
7 off the video record. That concludes DVD
8 Number 2. This time is 12:58.

9 (A luncheon recess is held from
10 12:58 p.m. to 1:37 p.m.)

11 THE VIDEOGRAPHER: We are now back
12 on the video record. This commences DVD
13 Number 3, August 18, 2016. The time 13:37.
14 BY MR. SCHULTZ:

15 Q. Good afternoon, Mr. Vigilante.
16 How much have you billed on this
17 case?

18 A. I had an invoice for \$11,021.50.

19 Q. Through what period of time?

20 A. That was through the report.

21 Q. First or second or both?

22 A. I'm going to say first report.

23 Q. All right. Do you know how much
24 you've -- the work value of your time since
25 then?

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<p>1 W. VIGILANTE</p> <p>2 A. I have got maybe another five to</p> <p>3 ten hours --</p> <p>4 Q. Okay. So --</p> <p>5 A. -- through today.</p> <p>6 Q. So another couple thousand?</p> <p>7 A. Yeah.</p> <p>8 Q. Thereabouts. Okay.</p> <p>9 Would you agree with me,</p> <p>10 Mr. Vigilante, that as an expert you have an</p> <p>11 obligation to gather and consider all relevant</p> <p>12 information in formulating your opinions?</p> <p>13 A. If it's available, sure.</p> <p>14 Q. Okay. And in the case of what</p> <p>15 you're opining on, information regarding human</p> <p>16 factors evaluations performed by Medtronics is</p> <p>17 certainly relevant; correct?</p> <p>18 A. Sure.</p> <p>19 Q. And it's your job as an expert to</p> <p>20 obtain and review and consider that</p> <p>21 information; right?</p> <p>22 A. If I know it's available and I can</p> <p>23 obtain it, sure.</p> <p>24 Q. Right. And there was information</p> <p>25 that was available, but you didn't consider it</p>	<p>1 W. VIGILANTE</p> <p>2 in your first report, correct, of that nature?</p> <p>3 A. Yeah, well, I think what you're</p> <p>4 referring to is that there was information I</p> <p>5 wasn't aware that was available when I wrote</p> <p>6 my first report.</p> <p>7 Q. Did you ask for all human factors</p> <p>8 evaluations performed by Medtronic during the</p> <p>9 design of the P-cap?</p> <p>10 A. I don't recall exactly what I</p> <p>11 asked for. I asked for relevant information.</p> <p>12 Q. Would you expect that that would</p> <p>13 be provided to you?</p> <p>14 A. Yeah. At the time I wrote my</p> <p>15 report, I thought I had relevant information</p> <p>16 that was available.</p> <p>17 Q. And you didn't; right?</p> <p>18 A. Well, if you're referring to the</p> <p>19 deposition of Mrs. --</p> <p>20 Q. Susan McConnell.</p> <p>21 A. -- Susan McConnell and the</p> <p>22 exhibits that went with it, I did not have</p> <p>23 them when I wrote my first report.</p> <p>24 Q. Right. And that's information</p> <p>25 that you would have liked to have had when you</p>
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<p>1 W. VIGILANTE</p> <p>2 formulated your initial opinions in this case;</p> <p>3 correct?</p> <p>4 A. If I knew it was available, I</p> <p>5 would have liked to have had it.</p> <p>6 Q. Well, whether or not you knew it</p> <p>7 was available, you would have liked to have</p> <p>8 had it; right?</p> <p>9 A. I'm sorry. I don't mean to argue</p> <p>10 with you, but if I didn't know it was</p> <p>11 available, I wouldn't know whether I would</p> <p>12 like it or not.</p> <p>13 Q. In -- you wouldn't know if you</p> <p>14 would like it or not?</p> <p>15 A. If I don't know it's available. I</p> <p>16 mean, we're getting into a Dick Cheney thing</p> <p>17 here where you can't know what you don't know.</p> <p>18 Q. Well, I understand that you didn't</p> <p>19 know it was available. You know it's</p> <p>20 available now; right?</p> <p>21 A. Yes, I do.</p> <p>22 Q. All right. And from having</p> <p>23 reviewed that information, you wouldn't argue</p> <p>24 with me that it's relevant to your opinions;</p> <p>25 correct?</p>	<p>1 W. VIGILANTE</p> <p>2 A. To parts of them, yes.</p> <p>3 Q. Right. And so in retrospect, you</p> <p>4 would have wished that it had been provided to</p> <p>5 you before you formulated your opinions in</p> <p>6 this case?</p> <p>7 A. As I said a little bit ago, if I</p> <p>8 knew it was available, I would have liked to</p> <p>9 have had it.</p> <p>10 Q. Right. You're not a design</p> <p>11 engineer; correct?</p> <p>12 A. I am not an engineer.</p> <p>13 Q. All right. You're not offering</p> <p>14 opinions on the design of the P-cap; correct?</p> <p>15 A. As it relates to the overall</p> <p>16 product design and where warnings fit in, I</p> <p>17 am. With respect to the specific design, I'm</p> <p>18 not.</p> <p>19 Q. Well, let me put it a different</p> <p>20 way.</p> <p>21 You're not offering opinions on</p> <p>22 the physical design of the P-cap itself as</p> <p>23 distinct from how the instructions or warnings</p> <p>24 should have been written in your opinion?</p> <p>25 A. I'm not sure what you're asking</p>

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<p>1 W. VIGILANTE</p> <p>2 me.</p> <p>3 Q. Okay. I'll rephrase it.</p> <p>4 You're not offering an opinion</p> <p>5 that it was somehow an inappropriate design</p> <p>6 from an engineering perspective to include a</p> <p>7 venting mechanism in the P-cap; correct?</p> <p>8 A. Oh, yeah, I'm not offering</p> <p>9 opinions with respect to specific design</p> <p>10 features of it.</p> <p>11 Q. Right.</p> <p>12 A. I would iss -- I would deal with</p> <p>13 design issues as they fall into the overall</p> <p>14 safety hierarchy when dealing with product</p> <p>15 design. So the term "design" has a lot of</p> <p>16 connotations. I just want to make sure that</p> <p>17 we're on the same page with them.</p> <p>18 Q. No, I understand. Taking the</p> <p>19 design of -- or the design features of the</p> <p>20 P-cap itself, you were then looking at it from</p> <p>21 the perspective of whether the instructions</p> <p>22 and the warnings were adequate; correct?</p> <p>23 A. Yeah, given the design of the</p> <p>24 product, I'm looking at whether the</p> <p>25 instructions and warnings were adequate.</p>	<p>1 W. VIGILANTE</p> <p>2 Q. And you're not offering an opinion</p> <p>3 on how the event that is the subject of this</p> <p>4 lawsuit occurred, are you?</p> <p>5 A. Oh, no. I'm leaving that to</p> <p>6 Dr. Klimowicz and others. I'm not rendering</p> <p>7 an opinion as to the -- the ability for air to</p> <p>8 travel between the membrane that was used and</p> <p>9 the types of materials that were used for that</p> <p>10 membrane when it's contaminated with insulin</p> <p>11 or other contaminants.</p> <p>12 Q. So you're taking it as a given in</p> <p>13 formulating your opinions that Rachel Dennert</p> <p>14 suffered hypoglycemia as a result of something</p> <p>15 known as temporary blocked vent or prime/fill</p> <p>16 anomaly, you're just assuming that as a given;</p> <p>17 correct?</p> <p>18 MR. HAVERTY: Objection, if you're</p> <p>19 making any assumptions at all.</p> <p>20 A. Yeah, it's my understanding that</p> <p>21 that's what happened.</p> <p>22 Q. Well, what's -- your understanding</p> <p>23 that that, in fact, happened or are you taking</p> <p>24 as an assumption that that's what others</p> <p>25 believe happened?</p>
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<p>1 W. VIGILANTE</p> <p>2 A. That's what my understanding is</p> <p>3 others have concluded.</p> <p>4 Q. Okay. And you're not quarreling</p> <p>5 with that and you're not taking a side with</p> <p>6 that. You're taking that as a -- as a</p> <p>7 starting point for your opinions about</p> <p>8 instructions and warnings; correct?</p> <p>9 MR. HAVERTY: Objection.</p> <p>10 A. No. What I'm taking as a starting</p> <p>11 point is the fact that Medtronic identified</p> <p>12 the prime/fill anomaly; and, in fact, it was</p> <p>13 foreseeable when they were designing and</p> <p>14 developing it back in the late '90s, early</p> <p>15 2000s before Ms. Dennert was ever prescribed</p> <p>16 the -- the products.</p> <p>17 Q. Well, are you or are you not</p> <p>18 assuming that Rachel Dennert's hypoglycemia on</p> <p>19 August 8 of 2009 resulted from a condition</p> <p>20 known as temporary blocked vents?</p> <p>21 A. Yeah, my understanding is that at</p> <p>22 some point on the night prior to the being</p> <p>23 found, that the vents were blocked consistent</p> <p>24 with the prime/fill anomaly that Medtronic had</p> <p>25 identified, and that because of that she was</p>	<p>1 W. VIGILANTE</p> <p>2 administered an overdose of insulin or</p> <p>3 excessive amount of insulin and that related</p> <p>4 to whatever medical problems that she</p> <p>5 suffered.</p> <p>6 Q. And you would concede that you are</p> <p>7 not qualified to offer an opinion on whether,</p> <p>8 in fact, she had blocked vent membrane in her</p> <p>9 P-cap?</p> <p>10 MR. HAVERTY: And he won't offer any</p> <p>11 such opinion.</p> <p>12 A. Yeah, so two things. I don't know</p> <p>13 that I'm qualified or not, but I haven't been</p> <p>14 asked to do that and I wasn't planning on</p> <p>15 doing it.</p> <p>16 Q. Do you think you're qualified to</p> <p>17 render that opinion?</p> <p>18 A. I'd have to look at what the</p> <p>19 analysis was to -- to get involved with it and</p> <p>20 determine whether or not I am, but I haven't</p> <p>21 been asked to it, so it hasn't been anything</p> <p>22 that's been come up -- that has -- that has</p> <p>23 come up.</p> <p>24 Q. Would you agree that if, in fact,</p> <p>25 Rachel Dennert's hypoglycemia were not caused</p>

<p style="text-align: right;">Page 158</p> <p>1 W. VIGILANTE</p> <p>2 by a venting membrane blockage, then your</p> <p>3 opinions about instructions and warnings are</p> <p>4 not causally related to her event?</p> <p>5 A. Well --</p> <p>6 MR. HAVERTY: He's not --</p> <p>7 A. I'm sorry.</p> <p>8 MR. HAVERTY: Before you get -- he's</p> <p>9 not offering any causation opinions. He's</p> <p>10 offering opinions about warnings.</p> <p>11 MR. SCHULTZ: Have you read his</p> <p>12 report?</p> <p>13 MS. MARTINEZ: He is offering it.</p> <p>14 MR. SCHULTZ: He's offering several</p> <p>15 causation opinions.</p> <p>16 MR. HAVERTY: No. He's offer --</p> <p>17 MR. SCHULTZ: It's right there in</p> <p>18 his --</p> <p>19 MR. HAVERTY: He's offering --</p> <p>20 MR. SCHULTZ: Right there in his</p> <p>21 report, Kevin.</p> <p>22 MR. HAVERTY: Dave, his opinions are</p> <p>23 on the adequacy of the instructions for</p> <p>24 use, the warnings; and if you want to ask</p> <p>25 him if he's got opinions on causation,</p>	<p style="text-align: right;">Page 159</p> <p>1 W. VIGILANTE</p> <p>2 point -- point them to me.</p> <p>3 MR. SCHULTZ: Well, yeah, in point</p> <p>4 of fact, it doesn't matter what you think</p> <p>5 his opinions are. It's a proper question</p> <p>6 and I want an answer to it. But his report</p> <p>7 does, in fact, say that the failure to</p> <p>8 provide what he deems adequate instructions</p> <p>9 caused her event.</p> <p>10 MR. HAVERTY: Okay.</p> <p>11 MR. SCHULTZ: So go ahead and read</p> <p>12 my question back, please.</p> <p>13 (The following portion of the record</p> <p>14 is read by the Court Reporter:</p> <p>15 "QUESTION: Would you agree that if,</p> <p>16 in fact, Rachel Dennert's hypoglycemia were</p> <p>17 not caused by a venting membrane blockage,</p> <p>18 then your opinions about instructions and</p> <p>19 warnings are not causally related to her</p> <p>20 event?")</p> <p>21 A. Can I answer it?</p> <p>22 Q. Yeah.</p> <p>23 A. Okay. Yeah, so if she experienced</p> <p>24 some other condition unrelated to the</p> <p>25 prime/fill anomaly, then my opinions wouldn't</p>
<p style="text-align: right;">Page 160</p> <p>1 W. VIGILANTE</p> <p>2 be related, causally related, but they would</p> <p>3 still be valid with respect to the adequacy of</p> <p>4 the warnings, instructions provided by the</p> <p>5 defendants.</p> <p>6 Q. But they wouldn't be causally</p> <p>7 related to the issues in this case?</p> <p>8 MR. HAVERTY: He just said that.</p> <p>9 A. That's what I just said.</p> <p>10 MR. SCHULTZ: Well, but he also</p> <p>11 muddled his answer by saying they'd still</p> <p>12 be valid which is not what I asked.</p> <p>13 MR. HAVERTY: Well --</p> <p>14 Q. So I want a clear answer on the</p> <p>15 record. They wouldn't be causally related to</p> <p>16 the event at -- at issue in this lawsuit?</p> <p>17 MR. HAVERTY: Objection, asked and</p> <p>18 answered.</p> <p>19 A. Yeah, so if Rachel Dennert</p> <p>20 experienced some other problem or malfunction</p> <p>21 with the -- with the pump that wasn't related</p> <p>22 to the prime/fill anomaly, my opinions with</p> <p>23 respect to causation wouldn't apply, but my</p> <p>24 other opinions regarding the adequacy of the</p> <p>25 warnings and instructions provided with the</p>	<p style="text-align: right;">Page 161</p> <p>1 W. VIGILANTE</p> <p>2 IFU from the defendants would be -- would be</p> <p>3 applicable and would be valid.</p> <p>4 MR. SCHULTZ: Move to strike</p> <p>5 everything after "but."</p> <p>6 Q. And, of course, if Rachel</p> <p>7 Dennert's hypoglycemia was the result of some</p> <p>8 idiosyncrasy of her diabetes or idiopathic --</p> <p>9 idiopathically caused and not related to any</p> <p>10 alleged malfunction of the pump, again, your</p> <p>11 opinions would not be causally related to the</p> <p>12 events at issue in this lawsuit; correct?</p> <p>13 MR. HAVERTY: That's the same</p> <p>14 question you just asked, Dave.</p> <p>15 MR. SCHULTZ: No -- yeah, but he --</p> <p>16 MR. HAVERTY: Go ahead.</p> <p>17 MR. SCHULTZ: -- he also assumed</p> <p>18 that the only alternative was it was either</p> <p>19 a temporary blocked vent or some other</p> <p>20 malfunction.</p> <p>21 Q. And my point is: If it's no</p> <p>22 malfunction at all and merely a hypoglycemic</p> <p>23 event, then, again, your opinions about</p> <p>24 warnings and instructions would not be</p> <p>25 causally related to her injury?</p>

<p style="text-align: right;">Page 162</p> <p>1 W. VIGILANTE</p> <p>2 MR. HAVERTY: Objection, form.</p> <p>3 A. So I -- I think I understand what</p> <p>4 you're asking me. So if her injury was the</p> <p>5 result of not a failure or malfunction of the</p> <p>6 pump due to the prime/fill anomaly, my</p> <p>7 opinions with respect to causation would not</p> <p>8 apply, but my opinions with respect to the</p> <p>9 adequacy of the instructions and warnings</p> <p>10 provided by Medtronic and Unomedical would</p> <p>11 still apply.</p> <p>12 Q. Well, do you think they'd be</p> <p>13 admissible?</p> <p>14 MR. HAVERTY: Whoa. No, don't</p> <p>15 answer.</p> <p>16 MR. SCHULTZ: Well, he's -- he's</p> <p>17 offering -- hey, he's -- he's deciding he's</p> <p>18 going to speculate --</p> <p>19 MR. HAVERTY: Dave.</p> <p>20 MR. SCHULTZ: -- on the legal</p> <p>21 sufficiency --</p> <p>22 MR. HAVERTY: What?</p> <p>23 MR. SCHULTZ: -- of his opinion --</p> <p>24 MR. HAVERTY: No.</p> <p>25 MR. SCHULTZ: -- so I'm going to</p>	<p style="text-align: right;">Page 163</p> <p>1 W. VIGILANTE</p> <p>2 follow up.</p> <p>3 MR. HAVERTY: No. He's saying that</p> <p>4 to him as an expert, his opinions would</p> <p>5 still apply as to the adequacy of the</p> <p>6 warning. It's not a question of</p> <p>7 admissibility, Dave. You just asked him a</p> <p>8 legal question.</p> <p>9 MR. SCHULTZ: No, he just gave a</p> <p>10 legal answer.</p> <p>11 Q. Go ahead and answer my question.</p> <p>12 A. Yeah, so from my analysis and my</p> <p>13 standpoint whether or not Rachel Dennert ever</p> <p>14 existed or used the pump is irrelevant to my</p> <p>15 assessment of the adequacy of the warnings and</p> <p>16 instructions provided by the defendants with</p> <p>17 the Paradigm Reservoir infusion set. Whether</p> <p>18 or not they're accessible, if somehow or</p> <p>19 another her incident was caused by some other</p> <p>20 method or some other malfunction or some other</p> <p>21 problem, you know, I'll leave the judge to</p> <p>22 decide that. I -- but my opinions are still</p> <p>23 valid.</p> <p>24 Q. Do you have an understanding based</p> <p>25 on any of your information gathering or</p>
<p style="text-align: right;">Page 164</p> <p>1 W. VIGILANTE</p> <p>2 conversations with Mr. Klimowicz as to which</p> <p>3 infusion set is at issue of the two that were</p> <p>4 used on the night of August 8th, 2009?</p> <p>5 A. It's understanding that</p> <p>6 Dr. Klimowicz has concluded that the</p> <p>7 contamination of the P-cap occurred in the</p> <p>8 second change-out refilling of the night at</p> <p>9 around ten o'clock, eleven o'clock, whatever</p> <p>10 the time is; and that's when the contamination</p> <p>11 and blockage of the vent -- vents occurred.</p> <p>12 Q. All right. So just -- I just want</p> <p>13 to make sure that it's clear. Your</p> <p>14 understanding of how the event occurred comes</p> <p>15 from Mr. Klimowicz; correct?</p> <p>16 A. And the testimony of Rachel's</p> <p>17 mother.</p> <p>18 Q. Okay. As opposed to based upon</p> <p>19 some original investigation by yourself?</p> <p>20 A. Yeah. I did not do an</p> <p>21 investigation by myself to determine at which</p> <p>22 point in time the contamination and the</p> <p>23 blockage of the vents occur.</p> <p>24 Q. All right. In rendering your</p> <p>25 opinions in this case -- first of all, you</p>	<p style="text-align: right;">Page 165</p> <p>1 W. VIGILANTE</p> <p>2 produced two reports; correct?</p> <p>3 A. Yes.</p> <p>4 Q. An initial report dated, I</p> <p>5 believe, April 19th of 2016 and then a</p> <p>6 supplemental report; right?</p> <p>7 A. That's correct.</p> <p>8 Q. All right.</p> <p>9 (Exhibit Vigilante-10, Report of</p> <p>10 William J. Vigilante, Jr., PhD, CPE dated</p> <p>11 April 19, 2016, is marked for</p> <p>12 identification.)</p> <p>13 THE WITNESS: Thank you.</p> <p>14 (Exhibit Vigilante-11, letter dated</p> <p>15 June 16, 2016 addressed to Kevin Haverty,</p> <p>16 Esq., is marked for identification.)</p> <p>17 THE WITNESS: Thank you.</p> <p>18 Q. Mr. Vigilante, the court reporter</p> <p>19 has marked Exhibit Number 10 which is your</p> <p>20 April 19th initial report and Exhibit</p> <p>21 Number 11 which is your supplemental report;</p> <p>22 correct?</p> <p>23 A. That's what they appear to be.</p> <p>24 Q. Okay. Now, the second report, the</p> <p>25 supplemental report rendered two months later,</p>

<p style="text-align: right;">Page 166</p> <p>1 W. VIGILANTE</p> <p>2 that was the one that you generated as a</p> <p>3 result of being provided with the deposition</p> <p>4 and exhibits for the deposition of Susan</p> <p>5 McConnell; right?</p> <p>6 (Reporter clarification.)</p> <p>7 Q. Susan McConnell; right?</p> <p>8 A. I'm sorry. I missed your</p> <p>9 question.</p> <p>10 Q. Sure. You generated the</p> <p>11 supplemental report two months after your</p> <p>12 original report because in the interim you'd</p> <p>13 been given the deposition of Susan McConnell;</p> <p>14 right?</p> <p>15 A. Yeah. So after I wrote my first</p> <p>16 report, I was provided with the deposition of</p> <p>17 Susan McConnell Monta -- Montell -- Mont --</p> <p>18 how about we just do Susan McConnell -- and</p> <p>19 the exhibits that went along with that</p> <p>20 deposition.</p> <p>21 Q. And prior to -- well, at the time</p> <p>22 you wrote your initial report, Exhibit 10, you</p> <p>23 weren't aware of Susan McConnell or her</p> <p>24 deposition; right?</p> <p>25 A. That's correct.</p>	<p style="text-align: right;">Page 167</p> <p>1 W. VIGILANTE</p> <p>2 Q. Who is she?</p> <p>3 A. She was a MiniMed and later a</p> <p>4 Medtronic employee, and I don't have the exact</p> <p>5 job description, but I can look it up if you</p> <p>6 would prefer.</p> <p>7 Q. Well, do you have an understanding</p> <p>8 of generally what her job was at the time of</p> <p>9 the development of the P-cap?</p> <p>10 A. I did at the time I wrote the</p> <p>11 report. I'd have to look up my notes to see</p> <p>12 what her job description was.</p> <p>13 Q. Well, regardless of her job</p> <p>14 description, would you agree that she was</p> <p>15 involved in the risk analysis and human</p> <p>16 factors assessment related to the P-cap during</p> <p>17 its development?</p> <p>18 A. It -- it seems that she was</p> <p>19 involved in the human factors testing that was</p> <p>20 done in the early 2000s.</p> <p>21 Q. You would agree that that</p> <p>22 information is relevant to the subject matter</p> <p>23 on which you've been asked to opine in this</p> <p>24 case?</p> <p>25 A. Sure.</p>
<p style="text-align: right;">Page 168</p> <p>1 W. VIGILANTE</p> <p>2 Q. You didn't consider it at the time</p> <p>3 because you didn't have it at the time of your</p> <p>4 initial report?</p> <p>5 A. I didn't consider it because I</p> <p>6 didn't know it existed at the time of my</p> <p>7 initial report.</p> <p>8 Q. And when exactly did you learn of</p> <p>9 its existence? When were you provided that</p> <p>10 deposition?</p> <p>11 A. Sometime between April 19, 2016</p> <p>12 and June 16th, 2016.</p> <p>13 Q. Can you be more specific?</p> <p>14 A. I'm sorry. I can't at this point.</p> <p>15 Q. How long after receiving that</p> <p>16 report or that deposition did you write your</p> <p>17 supplemental report?</p> <p>18 A. Well, my supplemental report's</p> <p>19 dated June 16th, 2016.</p> <p>20 Q. Right. But how quickly after</p> <p>21 receiving the deposition did you write the</p> <p>22 report?</p> <p>23 A. I'm sorry. I don't know.</p> <p>24 Q. In essence, you write in your</p> <p>25 supplemental report -- well, in your first</p>	<p style="text-align: right;">Page 169</p> <p>1 W. VIGILANTE</p> <p>2 report you issued the opinion that Medtronic</p> <p>3 did not perform an adequate human factors</p> <p>4 evaluation of the P-cap; correct?</p> <p>5 A. Okay.</p> <p>6 Q. Is that true?</p> <p>7 A. Sure.</p> <p>8 Q. And then unbeknownst to you, there</p> <p>9 had been a human factors evaluation during the</p> <p>10 development of the P-cap, and you received</p> <p>11 that information in the form of the deposition</p> <p>12 testimony of Susan McConnell and the related</p> <p>13 exhibits; correct?</p> <p>14 A. Yes, so my understanding when I</p> <p>15 wrote the initial report, all the other</p> <p>16 Medtronic, MiniMed employees and Unomedical</p> <p>17 employees testified that there was no human</p> <p>18 factors assessment done on the products that</p> <p>19 they were aware of. So at the time I wrote</p> <p>20 the report, I wasn't aware that any, any human</p> <p>21 factors was done or any risk analysis was done</p> <p>22 according to the guy who designed the P-cap</p> <p>23 system, Mr. Adair.</p> <p>24 Q. Well, to be --</p> <p>25 A. So when I wrote my report, that</p>

<p style="text-align: right;">Page 170</p> <p>1 W. VIGILANTE</p> <p>2 was my understanding. I have since -- since</p> <p>3 writing that report I learned that Susan</p> <p>4 McConnell had been deposed and she testified</p> <p>5 that there was a human factors study, two</p> <p>6 studies done in the early 2000s; and those --</p> <p>7 reports from those studies were produced as</p> <p>8 exhibits -- or as an exhibit.</p> <p>9 Q. And to be precise, I mean, you did</p> <p>10 read the deposition of Randy Adair, did you</p> <p>11 not?</p> <p>12 A. Yes.</p> <p>13 Q. And to be precise, he testified</p> <p>14 that he was not involved in any human factors</p> <p>15 studies; correct?</p> <p>16 A. Hold on a minute. I'll tell you</p> <p>17 what his testimony is.</p> <p>18 (Reviewing document.)</p> <p>19 He testified he did not do any</p> <p>20 human factors testing in the design of the</p> <p>21 P-cap on Page 71. He testified he does not</p> <p>22 know if any human factors testing was done on</p> <p>23 the P-cap on Page 71. He does not know if</p> <p>24 MiniMed did any safety testing on the P-cap on</p> <p>25 71.</p>	<p style="text-align: right;">Page 171</p> <p>1 W. VIGILANTE</p> <p>2 He was not involved in any risk</p> <p>3 analysis for the infusion sets used in the 511</p> <p>4 system, Page 92.</p> <p>5 He was not responsible for</p> <p>6 identifying potential risk associated with his</p> <p>7 design of the P-cap, Pages 122 to 123. He had</p> <p>8 never had any discussions with anyone who was</p> <p>9 responsible for identifying potential risk</p> <p>10 associated with his design of the P-cap, Page</p> <p>11 122.</p> <p>12 So there -- that's my summary of</p> <p>13 his deposition testimony.</p> <p>14 Q. So Mr. Adair testified that he was</p> <p>15 not involved in any human factors analysis and</p> <p>16 he didn't know whether one was done or not?</p> <p>17 A. That's not correct.</p> <p>18 Q. How is that incorrect?</p> <p>19 A. He does not know if any human</p> <p>20 factors testing was done and he did not do any</p> <p>21 human factors testing --</p> <p>22 Q. Right. And --</p> <p>23 A. -- on the design of the P-cap.</p> <p>24 Q. And based on that, you criticize</p> <p>25 Medtronic in your first report saying that</p>
<p style="text-align: right;">Page 172</p> <p>1 W. VIGILANTE</p> <p>2 they hadn't done any human factors testing,</p> <p>3 didn't you?</p> <p>4 A. I'm sorry. There was other</p> <p>5 testimony from other employees of Medtronic</p> <p>6 and Unomedical.</p> <p>7 Q. Answer my question, please.</p> <p>8 You -- you criticized Medtronic</p> <p>9 saying that they had not done any human</p> <p>10 factors analysis in the development of the</p> <p>11 P-cap; true?</p> <p>12 A. One more time 'cause I was waiting</p> <p>13 for another part to your question.</p> <p>14 Q. In your initial report you</p> <p>15 criticized Medtronic for failing to do any</p> <p>16 human factors analysis during the development</p> <p>17 of the P-cap --</p> <p>18 A. Yes --</p> <p>19 Q. -- true?</p> <p>20 A. -- during my initial report, it</p> <p>21 was my belief and understanding that they had</p> <p>22 not done any human factors testing, but it was</p> <p>23 not based solely on Randy Adair's testimony.</p> <p>24 It was based upon his testimony and other</p> <p>25 employees' testimony.</p>	<p style="text-align: right;">Page 173</p> <p>1 W. VIGILANTE</p> <p>2 Q. And you criticized Medtronic</p> <p>3 saying that they didn't do any; correct?</p> <p>4 A. Sure.</p> <p>5 Q. And you were wrong, they did,</p> <p>6 didn't they?</p> <p>7 A. After writing my report, I had</p> <p>8 learned that there was two human factors tests</p> <p>9 done on the IFU for the Paradigm pump --</p> <p>10 excuse me, Paradigm Reservoir infusion set.</p> <p>11 Q. So that was a false criticism on</p> <p>12 your part.</p> <p>13 A. I think it --</p> <p>14 Q. It was an inaccurate one.</p> <p>15 A. Sure. Inaccurate is probably a</p> <p>16 good word.</p> <p>17 Q. Okay. And it was unfair, wasn't</p> <p>18 it?</p> <p>19 MR. HAVERTY: Objection. Dave, save</p> <p>20 that for the jury, Dave.</p> <p>21 MR. SCHULTZ: No, no, it's --</p> <p>22 MR. HAVERTY: That's argument.</p> <p>23 MR. SCHULTZ: -- it's a question.</p> <p>24 MR. HAVERTY: That's argument.</p> <p>25 Q. Do you think it was unfair?</p>

<p style="text-align: right;">Page 174</p> <p>1 W. VIGILANTE</p> <p>2 A. I --</p> <p>3 MR. HAVERTY: That's a different</p> <p>4 question.</p> <p>5 A. Yeah, I don't think it's unfair</p> <p>6 because I wasn't aware of it. If I was aware</p> <p>7 of it and I didn't use it, then it would be</p> <p>8 unfair. My report is based, as stated in my</p> <p>9 report, based upon the information I had</p> <p>10 available at the time. Should additional</p> <p>11 information become available, I'm happy to</p> <p>12 redo my analysis, relook at it, and determine</p> <p>13 whether or not my opinions still apply or not.</p> <p>14 Q. And -- and to be precise about it,</p> <p>15 the information was always available, it just</p> <p>16 wasn't given to you?</p> <p>17 A. I don't know that either, so I --</p> <p>18 I don't --</p> <p>19 Q. You know the date of</p> <p>20 Ms. McConnell's deposition, don't you?</p> <p>21 A. I know that I didn't have it.</p> <p>22 Whether or not it was available to Mr. Haverly</p> <p>23 or someone else prior to that, I -- I don't</p> <p>24 know. I wasn't privy to that information.</p> <p>25 Q. Have you read Ms. McConnell's</p>	<p style="text-align: right;">Page 175</p> <p>1 W. VIGILANTE</p> <p>2 deposition?</p> <p>3 A. Yes.</p> <p>4 Q. Are you aware that Mr. Haverly was</p> <p>5 present during the deposition?</p> <p>6 A. I -- you know what? I don't</p> <p>7 recall, but I can look.</p> <p>8 First of all, it's my</p> <p>9 understanding that that deposition was taken</p> <p>10 in the John Kubiak and Karen Kubiak matter on</p> <p>11 behalf of Carolyn Kubiak.</p> <p>12 Q. Are you unaware that it was</p> <p>13 cross-noticed in this case, the Dennert case?</p> <p>14 A. I wasn't done. So that's first</p> <p>15 thing I wanted to point out.</p> <p>16 And the second was whether or not</p> <p>17 Mr. Haverly was there, and apparently he was</p> <p>18 there --</p> <p>19 Q. Are you aware --</p> <p>20 A. -- but the --</p> <p>21 Q. -- that it was cross-noticed in</p> <p>22 the Dennert case?</p> <p>23 A. Yeah, I don't know what</p> <p>24 "cross-noticed" means.</p> <p>25 Q. Are you aware that it was taken in</p>
<p style="text-align: right;">Page 176</p> <p>1 W. VIGILANTE</p> <p>2 the year 2015?</p> <p>3 A. It was taken on June 23rd, 2015.</p> <p>4 Q. So well in advance of your first</p> <p>5 report?</p> <p>6 A. Yeah, it was done -- what's</p> <p>7 that -- ten months before my first report.</p> <p>8 Q. Okay. And having -- when you</p> <p>9 finally received it after your first report</p> <p>10 criticizing Medtronic for not having engaged</p> <p>11 in any human factors analysis, you then</p> <p>12 concluded that despite having conducted human</p> <p>13 factors analysis, didn't change your opinion,</p> <p>14 Medtronic was still deficient; is that</p> <p>15 correct?</p> <p>16 A. Yeah, my opinions haven't changed</p> <p>17 based upon that information. The IFU for the</p> <p>18 reservoir and the infusion set are still</p> <p>19 deficient.</p> <p>20 Q. Well, no, what I'm talking about</p> <p>21 is your first opinion which is Medtronic</p> <p>22 failed to conduct an adequate human factors</p> <p>23 evaluation; and initially your opinion was</p> <p>24 they didn't do it at all and then when you</p> <p>25 were proven wrong, that they did do it, you</p>	<p style="text-align: right;">Page 177</p> <p>1 W. VIGILANTE</p> <p>2 said, yeah, but it was still inadequate;</p> <p>3 right?</p> <p>4 A. Well, so you've misstated a few</p> <p>5 things. One is that that wasn't my first</p> <p>6 opinion, but it is my second opinion; and two,</p> <p>7 after looking at the human factors usability</p> <p>8 testing report, the testing it did was still</p> <p>9 inadequate. So, yes, after looking at what</p> <p>10 they did, what they did was inadequate.</p> <p>11 Having not done it was inadequate, but what</p> <p>12 they did was inadequate as well, so my</p> <p>13 opinions still hold.</p> <p>14 Q. That what was done was inadequate</p> <p>15 even though you didn't understand that, in</p> <p>16 fact, you were initially wrong about whether</p> <p>17 one had been done or not?</p> <p>18 A. Yeah, so whether or not I knew it</p> <p>19 had been done or not doesn't change the fact</p> <p>20 that it was an inadequate usability study</p> <p>21 done; and, you know, there's -- I'm happy to</p> <p>22 give you the reasons why it's inadequate.</p> <p>23 It's not like I just made it up. If it had</p> <p>24 been a -- a thorough usability study, my</p> <p>25 belief is that they would have caught this</p>

<p style="text-align: right;">Page 178</p> <p>1 W. VIGILANTE</p> <p>2 problem and they would have addressed it back</p> <p>3 in the early 2000s, not waiting until 2012,</p> <p>4 2013.</p> <p>5 Q. Well, let's -- I -- I want to come</p> <p>6 back to that, but let me ask you this: Have</p> <p>7 you reviewed Exhibits 8, 9 and 10 of Susan</p> <p>8 McConnell's deposition?</p> <p>9 A. Hold on a minute.</p> <p>10 (Reviewing computer.)</p> <p>11 Yes.</p> <p>12 Q. All right. All right. So why</p> <p>13 don't we turn to -- why don't you tell me what</p> <p>14 in your opinion was deficient about the human</p> <p>15 factors evaluation that was performed by</p> <p>16 Medtronic during the development of the P-cap.</p> <p>17 A. So in the report that was</p> <p>18 disclosed as McConnell-8, they discuss a task</p> <p>19 analysis that was done on the reservoir to</p> <p>20 infusion set connection, IFUs, and the</p> <p>21 process; and they identify two usability</p> <p>22 studies that were performed.</p> <p>23 So with regard to the task</p> <p>24 analysis, they identified ten tasks, but</p> <p>25 they -- there's no indication in the report</p>	<p style="text-align: right;">Page 179</p> <p>1 W. VIGILANTE</p> <p>2 that they broke those tasks down to identify</p> <p>3 the sub-step -- sub-steps that were required</p> <p>4 for each -- to complete each tasks. There's</p> <p>5 no indication of what information on behalf --</p> <p>6 that's needed by the user to complete each of</p> <p>7 the sub -- sub -- sub-steps.</p> <p>8 There's no indication that they</p> <p>9 identify what actions were needed to complete</p> <p>10 each of the sub-steps. There's no indication</p> <p>11 of whether each sub-step action is consistent</p> <p>12 with conventional norms, behavioral tendencies</p> <p>13 or user expectancies. There's no assessment</p> <p>14 of ease of use, comfort, stress, or efficiency</p> <p>15 for each task and sub-task. There's no</p> <p>16 assessment of the errors or mistakes that can</p> <p>17 be made for each sub -- each sub-step.</p> <p>18 There's no assessment of the consequence of</p> <p>19 said errors, for example, hazards such as the</p> <p>20 P-cap being blocked and over- or</p> <p>21 under-administration of insulin.</p> <p>22 For the solution for Task Number 7</p> <p>23 through the task analysis, which Task 7 was</p> <p>24 remove transfer guard from reservoir, it</p> <p>25 states, "The instructions describe how the</p>
<p style="text-align: right;">Page 180</p> <p>1 W. VIGILANTE</p> <p>2 transfer guard must be removed." However,</p> <p>3 that solution identified in the task analysis</p> <p>4 was never implemented in the IFU for the</p> <p>5 reservoir that was provided to Ms. Dennert.</p> <p>6 So those are the problems I identified with</p> <p>7 their task analysis.</p> <p>8 For their usability studies the</p> <p>9 big thing is is that they didn't use a</p> <p>10 representative population of users. They went</p> <p>11 in -- into Mini -- into MiniMed and selected</p> <p>12 employees. If you want to do usability</p> <p>13 testing to validate whether it can be used by</p> <p>14 your potential users, you don't go and pull</p> <p>15 the people that have experience with -- with</p> <p>16 these types of products. And I think there's</p> <p>17 a list of in -- in here of their demographics</p> <p>18 that first -- the first usability study all</p> <p>19 ten -- all ten subjects were employees of</p> <p>20 MiniMed in their Clinical Services Department,</p> <p>21 all possessed a thorough understanding of</p> <p>22 insulin infusion pump use, all had high</p> <p>23 experience with filling syringes, insulin</p> <p>24 pumps, and infusion sets, 60 percent were</p> <p>25 college degrees, 40 percent had some college.</p>	<p style="text-align: right;">Page 181</p> <p>1 W. VIGILANTE</p> <p>2 Ms. Dennert had never used a pump</p> <p>3 before, and I'm sure there are many pump users</p> <p>4 and infusion set users that had never used</p> <p>5 this type of product before, but yet they</p> <p>6 weren't represented in their usability</p> <p>7 studies.</p> <p>8 Q. Can you point to me -- can you --</p> <p>9 A. I'm not done.</p> <p>10 Q. Well, but you're --</p> <p>11 A. Well, I'm not done.</p> <p>12 Q. Well, but --</p> <p>13 A. You asked me a question.</p> <p>14 MR. HAVERTY: Let him answer the</p> <p>15 question.</p> <p>16 Q. No, you're -- you're being</p> <p>17 narrative.</p> <p>18 MR. HAVERTY: No, he's tell --</p> <p>19 Q. Okay. So I'm going to break it</p> <p>20 down.</p> <p>21 MR. HAVERTY: You asked a question.</p> <p>22 You asked a question.</p> <p>23 MR. SCHULTZ: Well, and I'm --</p> <p>24 MR. HAVERTY: He's telling you --</p> <p>25 MR. SCHULTZ: -- entitled to follow</p>

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<p>1 W. VIGILANTE 2 up. 3 MR. HAVERTY: No, he's -- 4 MR. SCHULTZ: Okay. 5 MR. HAVERTY: -- entitled to finish 6 his answer. You asked a question. You're 7 getting your answer. Go ahead, Bill. 8 MR. SCHULTZ: No, go -- no. 9 MR. HAVERTY: Bill. 10 MR. SCHULTZ: I'm going to ask a 11 question. 12 Q. Mr. Vigilante, can you point me 13 where in your report, either report, you 14 criticize Medtronic for utilizing what you are 15 now saying are an unrepresentative sample in 16 the usability study? Can you show me where 17 that is? 18 A. So the second major problem that I 19 identified -- 20 Q. Can you answer my question, 21 please? 22 A. -- in the usability studies -- 23 Q. In the report, please, show me 24 where that opinion is disclosed, please. 25 A. I'm sorry. I was trying to finish</p>	<p>1 W. VIGILANTE 2 my answer to the last question. 3 Q. Mr. Vigilante, answer the question 4 that is posed, please. 5 MR. HAVERTY: He's still answering 6 the question. 7 MR. SCHULTZ: No. 8 MR. HAVERTY: He didn't finish his 9 answer. 10 MR. SCHULTZ: Well -- 11 MR. HAVERTY: He's going to finish 12 his answer. 13 MR. SCHULTZ: I'm asking a new 14 question. 15 MR. HAVERTY: You can ask a new 16 question when he's finished his answer. 17 MR. SCHULTZ: Kevin -- 18 MR. HAVERTY: Dave -- 19 MR. SCHULTZ: -- it is not your 20 deposition. 21 MR. HAVERTY: Hey. 22 MR. SCHULTZ: And I am tired of the 23 speaking objections. 24 MR. HAVERTY: Let's get the judge on 25 the phone right now.</p>
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<p>1 W. VIGILANTE 2 MR. SCHULTZ: He is not 3 responsive -- 4 MR. HAVERTY: Let's get the judge -- 5 MR. SCHULTZ: -- and I'm sick -- go 6 ahead. 7 MR. HAVERTY: Get the judge on the 8 phone right now because you're not 9 letting -- 10 MR. SCHULTZ: I want an answer to 11 the question. 12 MR. HAVERTY: You -- you -- you 13 didn't let him finish the answer to your 14 first question, Dave. 15 MR. SCHULTZ: Because he started to 16 read the entire report into the record -- 17 MR. HAVERTY: He -- you asked -- 18 MR. SCHULTZ: -- which is not 19 responsive. 20 MR. HAVERTY: -- what the criticisms 21 were. 22 MR. SCHULTZ: Fine. Now -- 23 MR. HAVERTY: Yeah, please -- 24 MR. SCHULTZ: -- answer -- no. 25 Q. Answer my question, Mr. Vigilante.</p>	<p>1 W. VIGILANTE 2 MR. HAVERTY: And as soon as you 3 finish answering his question, Bill, go 4 back and an -- and finish your answer to 5 his first question. 6 A. So -- 7 Q. Where in your report have you 8 criticized Medtronic for failing to use what 9 you've determined is a representative sample 10 of users in the usability study? 11 A. Well, in the first report I wasn't 12 aware that any human factors or usability 13 study was done, so I wouldn't have been able 14 to assess it, evaluate it, and point out the 15 deficiencies in it. 16 The second, I don't believe that I 17 went into great detail of it other than the 18 point I was trying to make, that the second 19 major issue I had with it was that it didn't 20 assess the IFU that was shipped with 21 Mrs. Dennert's infusion set and reservoir. In 22 fact, when they did their usability study, 23 they made change -- they had an IFU they 24 started with, they made changes to it -- they 25 don't tell us what those changes were -- based</p>

<p style="text-align: right;">Page 186</p> <p>1 W. VIGILANTE</p> <p>2 upon some of the usability study; and then</p> <p>3 when they got done, they made additional</p> <p>4 changes and didn't tell us what those changes</p> <p>5 were and they never went back to validate</p> <p>6 whether or not the changes they made, whether</p> <p>7 they were effective or not.</p> <p>8 So if you're going to change</p> <p>9 something because you're having problems, you</p> <p>10 just don't throw it out there and hope for the</p> <p>11 best. You got to validate what -- what you've</p> <p>12 done works. So that was the -- the second</p> <p>13 major issue that I had with the usability</p> <p>14 studies.</p> <p>15 Q. Are you done?</p> <p>16 A. Yes, sir.</p> <p>17 Q. Good. Now, can you point me to</p> <p>18 anywhere in your supplemental report that you</p> <p>19 wrote after learning that Medtronic had, in</p> <p>20 fact, done a human factors evaluation where</p> <p>21 you assert that the usability study didn't use</p> <p>22 a proper study population?</p> <p>23 A. I don't believe I discussed</p> <p>24 that --</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 187</p> <p>1 W. VIGILANTE</p> <p>2 A. -- in the --</p> <p>3 Q. I don't think you did either.</p> <p>4 A. -- supplemental report.</p> <p>5 Q. Okay. Would you turn to your</p> <p>6 initial report, please?</p> <p>7 A. Sure.</p> <p>8 Q. In your segment on hazard</p> <p>9 evaluation you discuss that -- or your opinion</p> <p>10 is that Medtronic did not identify the hazard;</p> <p>11 correct?</p> <p>12 A. Well, I think that you're</p> <p>13 misstating a few things, so maybe we can</p> <p>14 clarify that and then we can figure out what</p> <p>15 my opinion was.</p> <p>16 So I have a section in my report</p> <p>17 entitled "Hazard Identification," and the</p> <p>18 opinion with that -- for that section is that</p> <p>19 the unintended delivery of insulin resulting</p> <p>20 from the blockage of the P-cap connector vents</p> <p>21 created a hazard to users of the Paradigm</p> <p>22 infusion set and reservoir.</p> <p>23 Q. What I'm trying to understand is</p> <p>24 what is the hazard that you are saying</p> <p>25 Medtronic failed to identify?</p>
<p style="text-align: right;">Page 188</p> <p>1 W. VIGILANTE</p> <p>2 A. Well, the hazard is the under- or</p> <p>3 over-delivery of insulin unintended --</p> <p>4 Q. As -- as a result --</p> <p>5 A. -- and unknown.</p> <p>6 Q. -- of?</p> <p>7 A. As a result -- well, it's a result</p> <p>8 of the blocked vented -- excuse me --</p> <p>9 Q. Okay.</p> <p>10 A. -- blocked vents.</p> <p>11 Q. So you would agree -- well,</p> <p>12 your -- your position is Medtronic failed to</p> <p>13 identify that hazard; right?</p> <p>14 A. Well, that's part of it. My other</p> <p>15 part of it is that it was foreseeable.</p> <p>16 Q. I know that's not your entire</p> <p>17 opinion.</p> <p>18 My question is: Are you saying</p> <p>19 that Medtronic failed to identify that hazard</p> <p>20 as you've defined the hazard? Are you saying</p> <p>21 that?</p> <p>22 A. Well, two things. One is that</p> <p>23 Medtronic defined the hazard. I'm agreeing</p> <p>24 with them and using that as my understanding</p> <p>25 of what the hazard is; and, two, my criticism</p>	<p style="text-align: right;">Page 189</p> <p>1 W. VIGILANTE</p> <p>2 is, is that it was identifiable prior to 2012</p> <p>3 and prior to 2009 and it was identifiable</p> <p>4 during -- should have been identifiable during</p> <p>5 the design process back in the early 2000s and</p> <p>6 late 1990s.</p> <p>7 Q. Mr. Vigilante, I would appreciate</p> <p>8 an answer to my question. So listen carefully</p> <p>9 to my question.</p> <p>10 A. Sorry.</p> <p>11 Q. Your criticism is that in 2 --</p> <p>12 among others, and we'll talk about all the</p> <p>13 others, in the year 2000, during the</p> <p>14 development of the P-cap, Medtronic failed to</p> <p>15 identify the hazard which is the unintended</p> <p>16 over- or under-delivery of insulin resulting</p> <p>17 from a temporary blocked vent condition;</p> <p>18 correct?</p> <p>19 Have I stated that correctly?</p> <p>20 A. I think my opinions are listed in</p> <p>21 my report. So you're trying to paraphrase and</p> <p>22 combine them and condense them and change</p> <p>23 them --</p> <p>24 Q. Is it inaccurate?</p> <p>25 A. -- but they -- the way you -- I --</p>

<p style="text-align: right;">Page 190</p> <p>1 W. VIGILANTE</p> <p>2 again, the -- the opinions are in my report.</p> <p>3 The opinions are, is that their failure to do</p> <p>4 an adequate risk and haz -- human factors</p> <p>5 analysis -- I'm sorry. The failure -- their</p> <p>6 failure to do an adequate risk and human</p> <p>7 factors analysis resulted in them failing to</p> <p>8 identify the hazard at the time of</p> <p>9 development --</p> <p>10 Q. Okay.</p> <p>11 A. -- and that had they --</p> <p>12 Q. So --</p> <p>13 A. -- done that, you know, they --</p> <p>14 they should have identified it and they should</p> <p>15 have dealt with it; and that their failure to</p> <p>16 do the -- a proper, adequate human factors</p> <p>17 analysis was unreasonably dangerous and</p> <p>18 created an unreasonably dangerous condition</p> <p>19 that caused or contributed to Mrs. Dennert's</p> <p>20 injuries.</p> <p>21 Q. Mr. Vigilante, I'm not trying to</p> <p>22 trick you here. Okay? And this deposition is</p> <p>23 going to take an awfully long time if every</p> <p>24 time I ask you one question, you regurgitate</p> <p>25 your entire opinion. Okay? So let me try it</p>	<p style="text-align: right;">Page 191</p> <p>1 W. VIGILANTE</p> <p>2 again and be specific and let's see if I can</p> <p>3 get an answer to my question.</p> <p>4 Among everything else you say in</p> <p>5 your report, you are asserting that Medtronic</p> <p>6 during the development of the P-cap failed to</p> <p>7 identify the hazard; correct?</p> <p>8 A. They did.</p> <p>9 Q. Okay. You would agree with me,</p> <p>10 would you not, that a manufacturer cannot warn</p> <p>11 of a hazard that they don't know about?</p> <p>12 A. Sure.</p> <p>13 Q. Okay. And your point is that they</p> <p>14 should have identified that hazard, broadly</p> <p>15 speaking, during the development; correct?</p> <p>16 Generally speaking, that's a</p> <p>17 correct statement; right?</p> <p>18 A. Yes, had they done an adequate</p> <p>19 human factors and risk analysis, they should</p> <p>20 have identified it.</p> <p>21 Q. Okay. But you would also agree</p> <p>22 that if, in fact, someone concludes that an</p> <p>23 adequate human factors evaluation was done,</p> <p>24 and that adequate human factors evaluation did</p> <p>25 not identify the hazard, then the failure to</p>
<p style="text-align: right;">Page 192</p> <p>1 W. VIGILANTE</p> <p>2 warn of that hazard is understandable; right?</p> <p>3 You'd agree with that?</p> <p>4 A. I would not because there's no</p> <p>5 reasonable person that can look at the</p> <p>6 usability testing that was done and consider</p> <p>7 it adequate.</p> <p>8 Q. There is no reasonable person who</p> <p>9 can look at the usability studies and the</p> <p>10 human factors analysis that were done and</p> <p>11 conclude that they were adequate?</p> <p>12 A. That's correct.</p> <p>13 Q. So if a -- if an expert testifying</p> <p>14 for Medtronic and employees testifying for</p> <p>15 Medtronic say that the human factors analysis</p> <p>16 and the usability testing that was done is</p> <p>17 adequate, they're unreasonable and wrong?</p> <p>18 A. That would be correct.</p> <p>19 Q. Okay. What standard that existed</p> <p>20 at the time of the development of the P-cap</p> <p>21 are you utilizing for this opinion?</p> <p>22 A. The standard of care for product</p> <p>23 design and development.</p> <p>24 Q. Well, what -- I mean, is there a</p> <p>25 published standard you're referring to?</p>	<p style="text-align: right;">Page 193</p> <p>1 W. VIGILANTE</p> <p>2 A. You can look at the -- the ANSI</p> <p>3 standards that talk about symbol and pic --</p> <p>4 pictograph development where they require</p> <p>5 comprehension and critical confusion testing,</p> <p>6 which wasn't done. That testing is done by a</p> <p>7 representative sample of the user population,</p> <p>8 which wasn't done. Testing also requires that</p> <p>9 you do it on the subject product with the</p> <p>10 subject warnings, instructions, or whatever</p> <p>11 you're providing, and that wasn't done.</p> <p>12 This isn't a -- this isn't</p> <p>13 launching a rocket to the moon. This is</p> <p>14 pretty simple stuff here. If you're going to</p> <p>15 do a usability study quote-unquote, it should</p> <p>16 be with the people that are likely to use the</p> <p>17 product, not your employees who've got a lot</p> <p>18 of experience in the field. And if you're</p> <p>19 going to assert that the IFU that you created</p> <p>20 is adequate, you need to make sure that IFU is</p> <p>21 the one that -- is the one that you tested and</p> <p>22 not some other earlier revision that you</p> <p>23 changed and have no idea what the effects of</p> <p>24 those change are.</p> <p>25 Q. Would you look at Page 8 of your</p>

<p style="text-align: right;">Page 194</p> <p>1 W. VIGILANTE</p> <p>2 initial report?</p> <p>3 A. Sure.</p> <p>4 Q. In the first full paragraph on</p> <p>5 that page you write, "Once the user attaches</p> <p>6 the insulin to the opposite side of the</p> <p>7 transfer guard" --</p> <p>8 A. I'm sorry. I got to find it.</p> <p>9 Your -- top paragraph you said?</p> <p>10 Q. Middle of the top paragraph.</p> <p>11 A. Okay. And it starts where?</p> <p>12 Q. It says, "Once the user attaches</p> <p>13 the insulin" --</p> <p>14 A. Okay.</p> <p>15 Q. -- "to the opposite side of the</p> <p>16 transfer guard, they have to hold the</p> <p>17 reservoir upright and the insulin vial upside</p> <p>18 down."</p> <p>19 A. Yes.</p> <p>20 Q. Is -- is that a true statement?</p> <p>21 A. Yes and no.</p> <p>22 Q. Okay. How is it true? How is it</p> <p>23 not?</p> <p>24 A. It's true in the IFU that's in</p> <p>25 this pack that was relevant to the one</p>	<p style="text-align: right;">Page 195</p> <p>1 W. VIGILANTE</p> <p>2 Ms. Dennert was using, but it's not true for</p> <p>3 the IFU they tested back in the early 2000s.</p> <p>4 In the early 2000s they tested it with the IFU</p> <p>5 telling you to keep the insulin bottle on the</p> <p>6 table. So, again, they changed the IFU. They</p> <p>7 changed the instructions at some point in time</p> <p>8 after that testing was done and they never</p> <p>9 validated what effect that would have on</p> <p>10 compliance and understanding and action.</p> <p>11 Q. This is for the purposes of</p> <p>12 pressurizing the vial, correct, this step?</p> <p>13 A. It's both for pressurizing the</p> <p>14 vial and for filling the reservoir or</p> <p>15 extracting the insulin from the vial into the</p> <p>16 reservoir or, you know, fill the reservoir.</p> <p>17 Q. Okay. Why do you say that that's</p> <p>18 different from the IFU that was tested?</p> <p>19 A. Because that's what the -- that's</p> <p>20 what is noted in the IFU usability -- excuse</p> <p>21 me. That's what's noted in the usability</p> <p>22 report that was disclosed as Exhibit 8 in</p> <p>23 Susan McConnell's deposition.</p> <p>24 Q. Okay. Next -- in this same</p> <p>25 paragraph, you say, (as read): "However, if</p>
<p style="text-align: right;">Page 196</p> <p>1 W. VIGILANTE</p> <p>2 the reservoir is removed while the insulin</p> <p>3 vial is inverted, the insulin can squirt out</p> <p>4 due to the increased pressure in the vial and</p> <p>5 contaminate the top of the reservoir."</p> <p>6 Are you forgetting anything in</p> <p>7 that step?</p> <p>8 A. I was looking at something before</p> <p>9 you started reading, so I lost the place. If</p> <p>10 you wouldn't mind redoing that...</p> <p>11 Q. Last sentence of the first</p> <p>12 paragraph of your report on Page 8.</p> <p>13 A. Okay.</p> <p>14 I'm sorry. Is there a question or</p> <p>15 did you want me to read it?</p> <p>16 Q. Have you read it?</p> <p>17 A. That's what I was asking. I</p> <p>18 didn't know if you were going to read it.</p> <p>19 (Reviewing document.)</p> <p>20 Okay. I read it.</p> <p>21 Q. Is that true in all cases?</p> <p>22 A. It's not true in all cases. It</p> <p>23 depends upon the amount of insulin and the</p> <p>24 amount of air that's pumped into the insulin</p> <p>25 vial when the reservoir is removed.</p>	<p style="text-align: right;">Page 197</p> <p>1 W. VIGILANTE</p> <p>2 Q. All right. If the insulin vial is</p> <p>3 over-pressurized in other words?</p> <p>4 A. If there's enough pressure to</p> <p>5 cause the insulin that's remaining in the</p> <p>6 insulin vial to be pushed out, so</p> <p>7 over-pressurized, yeah, I think that's, again,</p> <p>8 a fuzzy word that I'm not comfortable using</p> <p>9 because it hasn't been defined.</p> <p>10 Q. Do you have an understanding of</p> <p>11 how the user is supposed to use the reservoir</p> <p>12 to pressurize the vial?</p> <p>13 A. Yeah, it's my understanding is</p> <p>14 that they connect the insulin vial to the</p> <p>15 other half of the transfer guard and they push</p> <p>16 the plunger in of the reservoir to inject air</p> <p>17 into the insulin vial and then to pull the</p> <p>18 plunger out to extract the insulin into the</p> <p>19 reservoir.</p> <p>20 Q. But are -- do you have an</p> <p>21 understanding of how they're supposed to</p> <p>22 determine how much to pressurize the vial?</p> <p>23 A. That's not provided in any of the</p> <p>24 instructions I've seen.</p> <p>25 Q. Okay. So you don't have an</p>

<p style="text-align: right;">Page 198</p> <p>1 W. VIGILANTE</p> <p>2 understanding of that?</p> <p>3 A. My understanding is that</p> <p>4 Medtronic, MiniMed, Unomedical didn't tell</p> <p>5 users in the IFU how much pressure to put in.</p> <p>6 Q. Okay.</p> <p>7 MR. SCHULTZ: Sorry?</p> <p>8 MS. MARTINEZ: No.</p> <p>9 MR. SCHULTZ: Okay.</p> <p>10 Q. Mr. Vigilante, you write in this</p> <p>11 Page 8 of your first report that "The user" --</p> <p>12 this is now in the third full paragraph,</p> <p>13 middle of the paragraph, "The user is</p> <p>14 instructed to hold the button until they see</p> <p>15 insulin dripping from the end of the infusion</p> <p>16 set QD."</p> <p>17 What do you mean by "QD" first of</p> <p>18 all?</p> <p>19 A. The quick detach on the cannula.</p> <p>20 Q. Oh, okay. So -- and that's --</p> <p>21 what you're describing is part of the manual</p> <p>22 prime process; right?</p> <p>23 A. That's my understanding.</p> <p>24 Q. Right. And to your knowledge, the</p> <p>25 user can see insulin dripping from the end of</p>	<p style="text-align: right;">Page 199</p> <p>1 W. VIGILANTE</p> <p>2 the infusion set; correct?</p> <p>3 A. During the prime process.</p> <p>4 Q. Right. And if they take their</p> <p>5 finger off the button and insulin continues to</p> <p>6 drip from the end of the infusion set, that is</p> <p>7 also visible; correct?</p> <p>8 A. Sure.</p> <p>9 Q. Okay.</p> <p>10 A. If they're looking for it.</p> <p>11 Q. It's visible; right?</p> <p>12 A. If they're looking for it, it's</p> <p>13 visible. I will agree with you. I'm not</p> <p>14 trying to argue with you, but you're using --</p> <p>15 Q. No, actually --</p> <p>16 A. -- using terms --</p> <p>17 Q. -- you are arguing --</p> <p>18 A. -- very loosely.</p> <p>19 Q. -- with me. I asked you a</p> <p>20 specific question and you want to give a</p> <p>21 speech, and I'd appreciate it if you'd answer</p> <p>22 my question.</p> <p>23 It's visible.</p> <p>24 A. If you look --</p> <p>25 Q. Whether they see it or not, which</p>
<p style="text-align: right;">Page 200</p> <p>1 W. VIGILANTE</p> <p>2 is what you volunteered, is a different</p> <p>3 question; right?</p> <p>4 A. I'm sorry. I --</p> <p>5 Q. It's visible.</p> <p>6 MR. HAVERTY: What's visible? The</p> <p>7 insulin?</p> <p>8 Q. The insulin dripping from the end</p> <p>9 of the infusion set, it's visible.</p> <p>10 A. It's visible to the patient if</p> <p>11 they're looking for it, yes.</p> <p>12 Q. It's visible.</p> <p>13 A. If they are looking away from it,</p> <p>14 it is not visible, it cannot be visible. It's</p> <p>15 just like a tree dropping in the woods does</p> <p>16 not make a sound because there's nobody here</p> <p>17 to hear it because sound is a perceptual</p> <p>18 process. If you're not looking for it, you</p> <p>19 can't see it.</p> <p>20 Q. Okay. If you -- if -- if you</p> <p>21 don't see it, it's not visible?</p> <p>22 A. Well, how about this? Because of</p> <p>23 your loose use of the terms, we can say it's</p> <p>24 detectable.</p> <p>25 Q. I'm being loose?</p>	<p style="text-align: right;">Page 201</p> <p>1 W. VIGILANTE</p> <p>2 A. You are ver -- being very loose in</p> <p>3 your terms.</p> <p>4 Q. I see. Okay.</p> <p>5 A. So it's detectable. How about</p> <p>6 that?</p> <p>7 Q. I would --</p> <p>8 A. That -- that would be the correct</p> <p>9 word. It's detectable, and I will agree with</p> <p>10 you.</p> <p>11 Q. Because it's visible to anybody</p> <p>12 looking at it; right?</p> <p>13 MR. HAVERTY: That's what he said to</p> <p>14 you.</p> <p>15 A. No, it's detectable, but if you're</p> <p>16 looking at it, it is visible.</p> <p>17 Q. All right.</p> <p>18 A. You can see it if you're looking</p> <p>19 at it.</p> <p>20 How about we take a break? We've</p> <p>21 been going about an hour.</p> <p>22 Q. No, I'm not ready to take a break.</p> <p>23 A. Well --</p> <p>24 Q. Do you need one --</p> <p>25 A. Yes.</p>

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<p>1 W. VIGILANTE</p> <p>2 Q. -- for some reason?</p> <p>3 A. 'Cause it's been about an hour.</p> <p>4 I'll ask you -- if you got another question</p> <p>5 you want to ask, I'm happy to --</p> <p>6 Q. I have many questions to you ask,</p> <p>7 Mr. Vigilante.</p> <p>8 A. Then let's take --</p> <p>9 Q. If you need a break --</p> <p>10 A. Let's --</p> <p>11 Q. -- we can take a break.</p> <p>12 A. Yeah, that will work. Thank you.</p> <p>13 THE VIDEOGRAPHER: We are now going</p> <p>14 off the video record. The time is 14:29.</p> <p>15 (A recess is held from 2:29 p.m. to</p> <p>16 2:38 p.m.)</p> <p>17 THE VIDEOGRAPHER: Back on, 14:39.</p> <p>18 BY MR. SCHULTZ:</p> <p>19 Q. All right. Mr. Vigilante, in a</p> <p>20 moment I want to get into the details of the</p> <p>21 criticisms that you narrated earlier about the</p> <p>22 task analysis and the IFU. Okay? And I want</p> <p>23 to get into that in a second, but before we do</p> <p>24 that, let me ask you: Would you agree that a</p> <p>25 medical device manufacturer or for that matter</p>	<p>1 W. VIGILANTE</p> <p>2 any manufacturer of any product, even with</p> <p>3 what you would consider to be an adequate</p> <p>4 human factors evaluation, will not identify</p> <p>5 all the ways in which somebody might misuse a</p> <p>6 product and/or cause themselves harm?</p> <p>7 A. Sure.</p> <p>8 Q. All right. And that, in fact, is</p> <p>9 the very theory behind the fact that the FDA</p> <p>10 requires post-market surveillance; right?</p> <p>11 A. Yeah, I'm not going to comment on</p> <p>12 what the F -- FDA's theory is. I don't know.</p> <p>13 Q. Okay. Well, do you understand</p> <p>14 that post-market surveillance is intended to</p> <p>15 disclose and then deal with hazards that were</p> <p>16 not identified at the time of development?</p> <p>17 A. Yeah, so the way you're describing</p> <p>18 it, it's no different than any other product</p> <p>19 where after you put it into the field you want</p> <p>20 to continue to monitor its use and problems</p> <p>21 that come up with its use so that you can</p> <p>22 identify problems that you missed in your risk</p> <p>23 analysis and human factors analysis.</p> <p>24 Q. Well, and not just that you</p> <p>25 missed, but that there's no reason why you</p>
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<p>1 W. VIGILANTE</p> <p>2 would have caught; right?</p> <p>3 A. It can be, sure. Anything is</p> <p>4 possible.</p> <p>5 Q. I mean, 'cause -- 'cause not all</p> <p>6 hazards and not all user errors are</p> <p>7 foreseeable, are they?</p> <p>8 A. Correct.</p> <p>9 Q. Okay. You said earlier that this</p> <p>10 hazard -- and I -- I just want to short</p> <p>11 circuit so that we can be efficient here.</p> <p>12 When I say "this hazard," I'm</p> <p>13 referring to the prime/fill anomaly hazard.</p> <p>14 You said earlier that that was</p> <p>15 foreseeable to Medtronic in 2000; correct?</p> <p>16 A. Yes.</p> <p>17 Q. What -- what standard are you</p> <p>18 using to determine foreseeability?</p> <p>19 A. I base foreseeability on what can</p> <p>20 be discerned through an adequate risk</p> <p>21 assessment and haz -- or human factors</p> <p>22 assessment.</p> <p>23 Q. But how -- how can you decide what</p> <p>24 would have been foreseeable through a human</p> <p>25 factors evaluation? What -- what methodology</p>	<p>1 W. VIGILANTE</p> <p>2 or what objective basis can you point to for</p> <p>3 determining that it was foreseeable?</p> <p>4 A. Well, first you start with your</p> <p>5 risk analysis, and Randy Adair testified that</p> <p>6 he had all the knowledge he needed at the time</p> <p>7 he designed and developed that P-cap. What</p> <p>8 they didn't do is integrate that into the</p> <p>9 overall design development of the infusion</p> <p>10 set --</p> <p>11 Q. Well --</p> <p>12 A. -- and that was their mistake</p> <p>13 there. If they had Randy Adair part of that</p> <p>14 process, they would have had a better chance</p> <p>15 of finding it.</p> <p>16 Second, had they done a human</p> <p>17 factors assessment of the IFU that was</p> <p>18 provided to Ms. Dennert, they would have</p> <p>19 realized that people are pulling the reservoir</p> <p>20 out while the insulin vial is inverted and</p> <p>21 they would have found the same thing that they</p> <p>22 found -- let me think of the name, the</p> <p>23 gentleman's name. I'm sorry. I referenced</p> <p>24 him in my report and I can't think of his name</p> <p>25 offhand.</p>

<p style="text-align: right;">Page 206</p> <p>1 W. VIGILANTE</p> <p>2 Q. Mark Curtis?</p> <p>3 A. Is he the -- the lab test guy?</p> <p>4 Yeah, Mark Curtis. They would</p> <p>5 have found the same thing Mark Curtis did,</p> <p>6 that when you remove the Paradigm Reservoir</p> <p>7 with the insulin vial inverted, you get the</p> <p>8 potential for insulin to leak out.</p> <p>9 Q. Well, Mr. Vigilante, in fairness</p> <p>10 to Mr. Adair, he did not say, "We had all the</p> <p>11 knowledge necessary and we failed to integrate</p> <p>12 it." That's your interpretation of the</p> <p>13 testimony that he did give; correct?</p> <p>14 A. I can just tell you what he</p> <p>15 testified to.</p> <p>16 Q. That would be lovely. Let's stick</p> <p>17 to what he testified to 'cause he certainly</p> <p>18 didn't say it was foreseeable, did he?</p> <p>19 Did he?</p> <p>20 A. Give me a minute here and I'll --</p> <p>21 I'll pull you up his testimony.</p> <p>22 Q. Could you answer my question</p> <p>23 first? He didn't say that it was foreseeable</p> <p>24 in 2000, did he?</p> <p>25 A. I'm sorry. I'm trying to answer</p>	<p style="text-align: right;">Page 207</p> <p>1 W. VIGILANTE</p> <p>2 your question.</p> <p>3 Q. Can you answer that question? Did</p> <p>4 he or did he not?</p> <p>5 A. I'm trying to answer that. I</p> <p>6 don't know why you --</p> <p>7 Q. Did he say it was foreseeable?</p> <p>8 A. I'm sorry. I'm trying to --</p> <p>9 trying to answer your question.</p> <p>10 (Reviewing document.)</p> <p>11 He testify at Page 45, (as read):</p> <p>12 "From an engineering basis, if you have a</p> <p>13 device with a movable stopper/plunger and you</p> <p>14 apply an external pressure to the stopper, it</p> <p>15 will move."</p> <p>16 45, 46, (as read): "Theoretically</p> <p>17 possible the plunger could move without input</p> <p>18 from user if there is pressure differential."</p> <p>19 55, (as read): "Vents allow for</p> <p>20 flow or equalization of pressure, hydrophobic</p> <p>21 means hydro -- hydrophobic membrane does not</p> <p>22 allow liquid inside. There is an increased</p> <p>23 pressure in the reservoir as a result of the</p> <p>24 priming process."</p> <p>25 He did not consider that increased</p>
<p style="text-align: right;">Page 208</p> <p>1 W. VIGILANTE</p> <p>2 pressure in the reservoir occur -- occurs due</p> <p>3 to the priming process when he designed P-cap</p> <p>4 vents.</p> <p>5 Page 109, 110, (as read): "If</p> <p>6 pressure in housing exceed atmospheric</p> <p>7 pressure, resulting forces can cause reservoir</p> <p>8 piston to be driven inward, thus delivering</p> <p>9 unwanted insulin."</p> <p>10 111, (as read): "If user</p> <p>11 introduces pressure internally to housing</p> <p>12 through priming, that could cause piston, a</p> <p>13 plunger to deliver unwanted insulin if vent</p> <p>14 membrane is blocked."</p> <p>15 So that's apparently what he knew</p> <p>16 at the time.</p> <p>17 Q. Okay. And you equate that with</p> <p>18 knowledge of the hazard that went</p> <p>19 unrecognized; right?</p> <p>20 A. Well, no, he didn't recognize the</p> <p>21 hazard. That's why it was unrecognized.</p> <p>22 Q. Right. But you're saying that</p> <p>23 that was all the information necessary to</p> <p>24 recognize the hazard; right?</p> <p>25 A. No. In conjunction with the human</p>	<p style="text-align: right;">Page 209</p> <p>1 W. VIGILANTE</p> <p>2 factors analysis, they would have seen that</p> <p>3 people were likely to take the reservoir off</p> <p>4 with the insulin vial over it, resulting in</p> <p>5 the liquid getting on the interior of the</p> <p>6 P-cap. That, together with Randy Adair's</p> <p>7 knowledge, should have triggered to them that</p> <p>8 there is potential for a problem.</p> <p>9 Q. Is -- and no reasonable person can</p> <p>10 disagree with your statement that it was</p> <p>11 foreseeable in 2000?</p> <p>12 A. Assuming they did an adequate risk</p> <p>13 assessment and adequate risk -- human factors</p> <p>14 analysis, they should have foreseen it in</p> <p>15 2000.</p> <p>16 Q. Can a reasonable person disagree</p> <p>17 with you that even with whatever you consider</p> <p>18 to be an adequate human factors evaluation the</p> <p>19 hazard might not be identified?</p> <p>20 A. Yeah, I wouldn't consider that</p> <p>21 reasonable.</p> <p>22 Q. Okay. You, first of all, you have</p> <p>23 the benefit of hindsight; right?</p> <p>24 A. If you mean the fact that I'm</p> <p>25 involved in the issue after Medtronic</p>

<p style="text-align: right;">Page 210</p> <p>1 W. VIGILANTE</p> <p>2 identified it in 2012 and after they had a</p> <p>3 number of prime/fill anomalies recognized in</p> <p>4 their call data and the unfortunate incident</p> <p>5 with Ms. Dennert, yes.</p> <p>6 Q. Okay. So you now know that, in</p> <p>7 fact, this precise failure mechanism could</p> <p>8 occur; right?</p> <p>9 A. I do know that, yes.</p> <p>10 Q. All right. What, if anything,</p> <p>11 have you done to avoid hindsight bias in your</p> <p>12 analysis?</p> <p>13 A. I looked at what a reasonable risk</p> <p>14 assessment hazard analysis would have</p> <p>15 discerned.</p> <p>16 Q. Okay. Is there a standard we can</p> <p>17 point to that says objectively: "If you do</p> <p>18 all these steps, you will identify this"?</p> <p>19 A. There are standards, publications</p> <p>20 on how you do an adequate risk assessment and</p> <p>21 usability analysis; and if you follow those</p> <p>22 steps, it's there to be seen.</p> <p>23 Q. It's inevitable that they would</p> <p>24 have discovered this hazard?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 211</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay. Is there a concept of the</p> <p>3 frequency of a hazard occurring that is</p> <p>4 relevant to your determination of</p> <p>5 foreseeability?</p> <p>6 A. One more time 'cause I'm -- got --</p> <p>7 Q. Sure.</p> <p>8 A. -- lost in that question.</p> <p>9 Q. Does it matter -- does</p> <p>10 "foreseeability," as you use that phrase, take</p> <p>11 into account the likelihood that something</p> <p>12 will happen, the frequency of it?</p> <p>13 A. So, yes and no.</p> <p>14 Q. In what way "yes" and in what way</p> <p>15 "no"?</p> <p>16 A. Well, it has to have some</p> <p>17 frequency. If it didn't have any frequency,</p> <p>18 it would be, you know, not likely or not</p> <p>19 happening and then it wouldn't be foreseeable.</p> <p>20 But I think what you're confusing is, is that</p> <p>21 frequency is used as part of the assessment of</p> <p>22 risk, and risk is a function of -- of hazard</p> <p>23 severity, probability of occurrence or</p> <p>24 frequency and exposure rate. So frequency</p> <p>25 does play a part in your risk assessment, but</p>
<p style="text-align: right;">Page 212</p> <p>1 W. VIGILANTE</p> <p>2 not in the risk analysis.</p> <p>3 Q. Well, what I was trying to get at</p> <p>4 is: If something happens -- does it matter in</p> <p>5 your mind in terms of deciding whether</p> <p>6 something is foreseeable or reasonably</p> <p>7 foreseeable how -- hold on. The question is</p> <p>8 not done.</p> <p>9 A. Sure. Go ahead.</p> <p>10 Q. -- how frequently it happens?</p> <p>11 Does that matter?</p> <p>12 A. So from a design -- product design</p> <p>13 standpoint, you shouldn't have any of it</p> <p>14 happening because the product isn't released</p> <p>15 yet. So you need to foresee what could</p> <p>16 potentially happen, and part of your risk</p> <p>17 analysis is identifying the potential hazards;</p> <p>18 and then through your risk assessment you can</p> <p>19 rank those hazards on severity, exposure, and</p> <p>20 probab -- probability or likelihood and</p> <p>21 determine how you're going to deal with it.</p> <p>22 So when you do your risk</p> <p>23 assessment, things that are high risk, high</p> <p>24 hazard, you put more emphasis on. Things that</p> <p>25 are low risk, low hazard, maybe you don't</p>	<p style="text-align: right;">Page 213</p> <p>1 W. VIGILANTE</p> <p>2 catch on the first round, but you get it on</p> <p>3 the second round when you have the resources</p> <p>4 and time, or time and money, the resources</p> <p>5 including time and money.</p> <p>6 So frequency is a issue for</p> <p>7 assessing the level of risk, but not in</p> <p>8 identifying risk because you -- you're</p> <p>9 designing a new product. It's a -- it's a</p> <p>10 new -- new cap. It's a brand new cap, brand</p> <p>11 new vents. There's none in the -- in the --</p> <p>12 there's none in the market to judge what the</p> <p>13 frequency is.</p> <p>14 Q. Well, so then let's get at it at a</p> <p>15 different way.</p> <p>16 When you're doing this hazard</p> <p>17 evaluation or risk analysis, essentially,</p> <p>18 correct me if I'm wrong, I'm sure you will,</p> <p>19 that you're relying on people, the engineers,</p> <p>20 the human factors people, everybody involved</p> <p>21 in the process to think of every way somebody</p> <p>22 might misuse a product or use it incorrectly</p> <p>23 and every sequence of events that might follow</p> <p>24 from that that might lead to a hazard?</p> <p>25 A. Yeah, so what you're describing is</p>

<p style="text-align: right;">Page 214</p> <p>1 W. VIGILANTE</p> <p>2 both the failure modes effect analysis where</p> <p>3 you start with what is the -- if -- if</p> <p>4 something fails, the thing gets blocked, what</p> <p>5 are the consequences of that. That's exactly</p> <p>6 what it is.</p> <p>7 The fault tree analysis, you go</p> <p>8 back and deal with if -- what if something</p> <p>9 happened and -- and what are the -- the</p> <p>10 consequences of that. So you're talking about</p> <p>11 what a risk analysis is. That -- that's --</p> <p>12 that's what the engineers and the -- the human</p> <p>13 factors people and the other people in the</p> <p>14 Design Team, they're supposed to sit around</p> <p>15 and brainstorm what are the potential problems</p> <p>16 if X happens, if Y occurs, what is the result.</p> <p>17 And --</p> <p>18 Q. And it --</p> <p>19 A. -- certainly you have a new</p> <p>20 product, and this is why -- this is why I'm so</p> <p>21 emphatic that a reasonable person would</p> <p>22 conclude an adequate risk assessment or human</p> <p>23 factors assessment would have identified this.</p> <p>24 You have a new product. The --</p> <p>25 the product is the P-cap. Medtronic or</p>	<p style="text-align: right;">Page 215</p> <p>1 W. VIGILANTE</p> <p>2 MiniMed designed and developed it to replace</p> <p>3 an existing technology. You know, how did</p> <p>4 they -- how did they change it? The major</p> <p>5 change was its waterproof characteristics; and</p> <p>6 to get it waterproof, they had to put those</p> <p>7 vents in.</p> <p>8 So the engineer should have been</p> <p>9 sitting there, the Design Team should have</p> <p>10 been sitting there, well, what are the</p> <p>11 consequences of having these vents, what if</p> <p>12 the vents get blocked, What are the</p> <p>13 consequences of the vents getting blocked.</p> <p>14 Randy Adair testifies, "Eh, the</p> <p>15 vents get blocked, there's no pressure,</p> <p>16 pressure -- or no pressuriza -- no pressure</p> <p>17 equalization, you can have unwanted delivery</p> <p>18 of insulin." So it's not a -- it's not a huge</p> <p>19 leap. From an engineering standpoint, Adair</p> <p>20 knew the consequences. They just never</p> <p>21 bothered to sit down apparently to -- to think</p> <p>22 and do the -- the FMEA or the fault tree</p> <p>23 analysis to -- to put it together.</p> <p>24 We putting out a cap with vents on</p> <p>25 it. Nobody has ever done that before. What's</p>
<p style="text-align: right;">Page 216</p> <p>1 W. VIGILANTE</p> <p>2 the potential or the problems that can occur</p> <p>3 if the block -- if the vent gets blocked.</p> <p>4 Q. And if they, in that brainstorming</p> <p>5 process, they don't identify everything that</p> <p>6 can go wrong, they've simply failed in their</p> <p>7 job?</p> <p>8 A. If -- if they took reasonable</p> <p>9 steps, then they wouldn't have failed in the</p> <p>10 risk assessment, but, again, they've got the</p> <p>11 human factors assessment to back it up.</p> <p>12 Q. But what --</p> <p>13 A. So you're going to do the -- your</p> <p>14 usability testing. If you're doing it on the</p> <p>15 IFU that Rachel Dennert was provided, you're</p> <p>16 going to see that people are getting -- are</p> <p>17 removing the -- the reservoir from under the</p> <p>18 vial; and when it happens, depending upon the</p> <p>19 pressurization, you're either going to get a</p> <p>20 squirt out or you're going to get drops out,</p> <p>21 but you're going to get some fluid out if</p> <p>22 there's enough pressurization and insulin in</p> <p>23 the vial.</p> <p>24 So now you've identified another</p> <p>25 problem. Well, what just happened and what is</p>	<p style="text-align: right;">Page 217</p> <p>1 W. VIGILANTE</p> <p>2 the consequence of that? That -- that's the</p> <p>3 follow-on question. What is the consequence</p> <p>4 of that?</p> <p>5 So you take it back to your Design</p> <p>6 Team. If you're a human factors guy and you</p> <p>7 don't know what the consequences are, you take</p> <p>8 it back to the Design Team and let them deal</p> <p>9 with it. What are the consequences of getting</p> <p>10 the inside of the P-cap wet. Randy Adair will</p> <p>11 tell you, "Oh, it'll block the vent." Well,</p> <p>12 what are the consequences of that? Randy</p> <p>13 Adair will tell you, you can have no pressure</p> <p>14 equalization and you can get the reservoir</p> <p>15 plunger moving on its own.</p> <p>16 MR. SCHULTZ: Would you mark that?</p> <p>17 (Exhibit Vigilante-12, multipage</p> <p>18 document entitled Report of Protocol EP002</p> <p>19 and EP003: Usability Study of the Platform</p> <p>20 3 User-Filled Reservoir Assembly and Its</p> <p>21 Instructions for Use, is marked for</p> <p>22 identification.)</p> <p>23 THE WITNESS: Thank you.</p> <p>24 (Exhibit Vigilante-13, multipage</p> <p>25 document entitled ER-99-11-09-2256</p>

<p style="text-align: right;">Page 218</p> <p>1 W. VIGILANTE 2 Engineering Report, is marked for 3 identification.) 4 (Pause.) 5 COURT REPORTER: There's three? 6 MR. SCHULTZ: There's three, yeah, 7 and they're 12, 13, 14. 8 MR. HAVERTY: 12, 13, 14. 9 (Exhibit Vigilante-14, multipage 10 document entitled ER-99-12-13-2285 11 Engineering Report, is marked for 12 identification.) 13 Q. All right. Mr. Vigilante, the 14 court reporter has handed you Exhibits 12, 13 15 and 14 which correspond to Exhibits 8, 9 and 16 10 respectively from the deposition of Susan 17 McConnell. 18 A. Okay. 19 Q. Now, again, honestly, sir, you 20 have a tendency to give speeches that are not 21 responsive to my questions. So, you know, if 22 you can focus on my question and answer my 23 question, I'd appreciate it 'cause it's going 24 to take a long time if you don't. 25 MR. HAVERTY: Dave, ask a question.</p>	<p style="text-align: right;">Page 219</p> <p>1 W. VIGILANTE 2 MR. SCHULTZ: Well -- 3 MR. HAVERTY: Don't give a speech. 4 MR. SCHULTZ: Well -- 5 MR. HAVERTY: Don't give 6 instructions. 7 MR. SCHULTZ: That doesn't -- that 8 doesn't lie in your mouth. 9 MR. HAVERTY: It's your 10 deposition -- it's your -- 11 MR. SCHULTZ: Then be quiet. 12 MR. HAVERTY: -- deposition, Dave, 13 and you're entitled to ask questions only, 14 not make speeches and -- 15 MR. SCHULTZ: And you're not 16 entitled to make speeches and yet you do it 17 in every deposition all the time, so... 18 MR. HAVERTY: And I'll -- and I'll 19 wait until you do it when I'm taking the 20 depositions of your experts too, Dave, and 21 I'll make sure that I remind you that 22 you -- you're not supposed to either, so... 23 Q. So, Mr. Vigilante, if you can 24 answer my question, first of all, would you 25 agree that Exhibit 12 is, in fact, a human</p>
<p style="text-align: right;">Page 220</p> <p>1 W. VIGILANTE 2 factors evaluation? Is it one? 3 A. I'm sorry. 'Cause you -- you 4 sounded like you drifted off there and I 5 didn't catch what the last part of the 6 question was. 7 Q. Exhibit 8 -- 8 A. Yes. 9 Q. -- does that reflect that a human 10 factors analysis was performed? 11 A. Yes, in Vigilante-12, McConnell-8 12 is the report from the usability studies that 13 were conducted -- 14 Q. Now, if you look at -- 15 A. -- in 2000 and 2001. 16 Q. If you would look at Page 4, the 17 first -- and tell me if I've got it wrong, but 18 the steps that Medtronic went through, first 19 of all, were a task analysis followed by a 20 usability study; correct? 21 A. They did do a task analysis 22 followed by a usability study. 23 Q. And that is a proper sequence of 24 events to do, right, task analysis followed by 25 usability study?</p>	<p style="text-align: right;">Page 221</p> <p>1 W. VIGILANTE 2 A. I don't have any problem with the 3 sequence of it. 4 Q. All right. The task analysis you 5 are critical of, I think you said earlier, 6 because they didn't -- Medtronic did not break 7 each task down into sub-tasks; correct? 8 A. Correct. 9 Q. So, for example, on Page 4 of 10 Exhibit 12, Tasks Evaluated Number 7 says, 11 "Remove the transfer guard and medication vial 12 from the reservoir." 13 Do you see that? 14 A. Yes. 15 Q. And you criticize that because it 16 should have been broken down; is that right? 17 A. I criticize it because if they did 18 do that, they didn't document it and I don't 19 see it anywhere. 20 Q. Okay. How should that have been 21 broken down in your opinion? 22 A. Well, the -- I don't have the 23 benefit of having the IFU, but apparently 24 according to the next table, it involves the 25 unscrewing of the plunger rod and it includes</p>

<p style="text-align: right;">Page 222</p> <p>1 W. VIGILANTE</p> <p>2 pulling the plunger rod completely out of the</p> <p>3 reservoir and it includes --</p> <p>4 Q. Could you tell me where you're</p> <p>5 looking at?</p> <p>6 A. Yeah, you're talking about Step 8;</p> <p>7 right?</p> <p>8 Q. I'm talking about Step 7.</p> <p>9 A. I'm sorry. I apologize. So I was</p> <p>10 reading Step 8.</p> <p>11 So Step 7 on Page 6, there's a</p> <p>12 twist motion and then there's a pull motion.</p> <p>13 So they only -- you know, they identified the</p> <p>14 task, the -- the higher-level task, "Remove</p> <p>15 the transfer guard from the reservoir." But</p> <p>16 what are -- what steps are necessary to</p> <p>17 perform that task? And apparently there's a</p> <p>18 twisting motion and a pulling motion. And the</p> <p>19 twisting motion is in a certain direction. Of</p> <p>20 course, the pulling motion is also in a</p> <p>21 certain direction depending upon the</p> <p>22 orientation of the reservoir, but it's not</p> <p>23 identified.</p> <p>24 Q. And so your point is in this task</p> <p>25 of removing the reservoir from the transfer</p>	<p style="text-align: right;">Page 223</p> <p>1 W. VIGILANTE</p> <p>2 guard, they should break that into sub-tasks</p> <p>3 of twist the reservoir and pull; is that</p> <p>4 right?</p> <p>5 A. I would like to see the sub-steps.</p> <p>6 I would like to see the information necessary</p> <p>7 for the user to know what steps are required.</p> <p>8 I would like to see an assessment of the</p> <p>9 potential errors that could be made. I would</p> <p>10 like to see an assessment of whether or not</p> <p>11 the individual actions are consistent with</p> <p>12 norms, conventional norms, known behavioral</p> <p>13 tendencies and so forth.</p> <p>14 Q. Well, we're -- we're just</p> <p>15 talking -- or I was just talking about the</p> <p>16 task analysis for the moment.</p> <p>17 A. That is the task analysis.</p> <p>18 Q. Okay.</p> <p>19 A. This is the -- that's -- that's my</p> <p>20 point.</p> <p>21 Q. The task analysis includes</p> <p>22 usability as well?</p> <p>23 A. Well -- well, yes, it's a human</p> <p>24 factors analysis. It's -- it's -- you're</p> <p>25 looking at whether or not it's usable --</p>
<p style="text-align: right;">Page 224</p> <p>1 W. VIGILANTE</p> <p>2 Q. You don't --</p> <p>3 A. -- so you -- you need to know what</p> <p>4 needs to be done and whether or not what</p> <p>5 you're asking them to do is -- is -- is --</p> <p>6 would be defined as usable.</p> <p>7 Q. You don't distinguish between a</p> <p>8 task analysis and a usability study?</p> <p>9 A. Well, no. There is a difference</p> <p>10 between a task analysis and a usability study,</p> <p>11 but part of the task -- task analysis is to</p> <p>12 assess the usability of the steps. It's done</p> <p>13 by the professional human factors ergonomist.</p> <p>14 And part of the task assessment is</p> <p>15 looking at whether or not the actual</p> <p>16 individual steps would be considered usable or</p> <p>17 not based upon the comfort, efficiency, number</p> <p>18 of steps, whether or not it meets conventional</p> <p>19 norms, whether or not it meets users'</p> <p>20 expectations, whether or not the user needs</p> <p>21 any special knowledge or information to</p> <p>22 complete the task. That's all part of what</p> <p>23 the task analysis should be ferreting out.</p> <p>24 Q. So, I'm sorry. Then I -- I lost</p> <p>25 you. What is your criticism exactly in this</p>	<p style="text-align: right;">Page 225</p> <p>1 W. VIGILANTE</p> <p>2 task analysis and usability study? What is it</p> <p>3 that Medtronic didn't do that it was supposed</p> <p>4 to in your opinion?</p> <p>5 A. Yeah, well, number -- well, they</p> <p>6 identified the top tasks, but they didn't</p> <p>7 break it out, so we don't know whether or not</p> <p>8 they looked at the individual sub-steps or</p> <p>9 individual actions necessary to complete the</p> <p>10 task. There was no assessment as to what</p> <p>11 information the user needed to complete the</p> <p>12 sub -- the -- the actions or the task.</p> <p>13 So, for example, with Number 7 in</p> <p>14 the IFU that was assessed in the task</p> <p>15 analysis, which is Step Number 6 in the IFU</p> <p>16 that Mrs. Dennert was exposed to, you would</p> <p>17 need to know that you have to have the</p> <p>18 reservoir over the insulin vial to pull it out</p> <p>19 properly. So that's a piece of information</p> <p>20 that the task analysis should have identified</p> <p>21 because you're looking at the actions, what's</p> <p>22 required to be done, and then you're looking</p> <p>23 at, well, what knowledge does the user need to</p> <p>24 have to know how to do those actions.</p> <p>25 Then you need to look at whether</p>

<p style="text-align: right;">Page 226</p> <p>1 W. VIGILANTE</p> <p>2 or not the actions are consistent with, again,</p> <p>3 conventional norms, behavioral tendencies and</p> <p>4 so forth. You have to determine looking at it</p> <p>5 whether or not the action is going to be</p> <p>6 comfortable, whether or not it's going to be</p> <p>7 inducing any undue stress, whether or not it's</p> <p>8 going to be efficient or not; and I don't see</p> <p>9 any of that analysis in here.</p> <p>10 The other thing that task analysis</p> <p>11 looks at is you're breaking them down, those</p> <p>12 tasks down to sub-actions, what errors can</p> <p>13 occur. This is the part of the assessment,</p> <p>14 analysis that you're looking at potential</p> <p>15 errors. So it gets back to your hazard</p> <p>16 foreseeability and what is done from a product</p> <p>17 design standpoint to identify hazards. Well,</p> <p>18 the task analysis is done. And at these steps</p> <p>19 you're looking at, well, where -- where can</p> <p>20 they go wrong. If we're removing the</p> <p>21 reservoir from the transfer guard, what can</p> <p>22 they do wrong.</p> <p>23 They've got several sub-actions</p> <p>24 they have to do. One of the actions is make</p> <p>25 sure the reservoir is on top. Second is they</p>	<p style="text-align: right;">Page 227</p> <p>1 W. VIGILANTE</p> <p>2 have to twist. Third is they have to pull.</p> <p>3 Well, what can go wrong and where could they</p> <p>4 make a mistake or -- or deviate from what is</p> <p>5 required. Well, if they're supposed to take</p> <p>6 it off upside down, what happens if they take</p> <p>7 it off upside right. That's something that</p> <p>8 you would expect them to identify in the task</p> <p>9 analysis. And then as part of the task</p> <p>10 analysis is you're looking at what are the</p> <p>11 consequences of those errors, what are the</p> <p>12 hazards that can result because of those --</p> <p>13 because of those errors.</p> <p>14 So, again, if you're a human</p> <p>15 factors guy and you're doing your task</p> <p>16 analysis and you realize that they have to --</p> <p>17 we want them to do it with the vial below the</p> <p>18 reservoir, foreseeable that somebody is not</p> <p>19 going to do it that way, they're going to do</p> <p>20 it the other way. Maybe they're going to do</p> <p>21 it horizontally. What's the consequences.</p> <p>22 Well, if you're doing your task</p> <p>23 analysis, you see what the consequences are.</p> <p>24 The insulin comes out. Well, what's the</p> <p>25 consequence of that. If I don't know, then I</p>
<p style="text-align: right;">Page 228</p> <p>1 W. VIGILANTE</p> <p>2 got to take it to the engineer and say what's</p> <p>3 the consequence of the insulin coming out.</p> <p>4 And then you move it, you know, through the</p> <p>5 Development Team. But these are the types of</p> <p>6 things that you expect to be caught during the</p> <p>7 task analysis.</p> <p>8 Q. In your report, I -- and correct</p> <p>9 me if I'm wrong, you criticize Medtronic, at</p> <p>10 least as I understand it, for failing to</p> <p>11 recognize that the process of filling the</p> <p>12 reservoir requires the user to do -- I think</p> <p>13 you used the word "unnatural things" or, you</p> <p>14 know, stressful movements and things of that</p> <p>15 nature. You know what I'm referring to?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. Can you just very briefly</p> <p>18 tell me what is -- what is that critique, that</p> <p>19 you're saying that the way the process was set</p> <p>20 up, it was going to be difficult and</p> <p>21 uncomfortable for the user and, therefore,</p> <p>22 Medtronic should have seen why it would be</p> <p>23 done differently?</p> <p>24 A. What I'm saying is a couple things</p> <p>25 in the report, and I -- maybe I can</p>	<p style="text-align: right;">Page 229</p> <p>1 W. VIGILANTE</p> <p>2 demonstrate on the video since we're on video.</p> <p>3 Maybe I can talk about it too.</p> <p>4 This is the -- the reservoir</p> <p>5 attached to the transfer guard as it's shipped</p> <p>6 from Medtronic, and I believe it starts with</p> <p>7 the plunger retracted -- retracted.</p> <p>8 Part of the process is you put</p> <p>9 your insulin in. You -- you press --</p> <p>10 Q. Here, I'll tell you what: As long</p> <p>11 as you're going to demonstrate -- first of</p> <p>12 all, is it your testimony that this is</p> <p>13 unnatural, what they're being asked to do, or</p> <p>14 uncomfortable?</p> <p>15 A. Well, no, I'm getting to it.</p> <p>16 If -- if you allow me to finish, I can tell</p> <p>17 you what -- what the problems I have.</p> <p>18 Q. If you would allow me to set up</p> <p>19 the question, please.</p> <p>20 A. I was answering your last</p> <p>21 question.</p> <p>22 MR. HAVERTY: You're -- Dave, you</p> <p>23 did it again. You asked him the</p> <p>24 question --</p> <p>25 MR. SCHULTZ: Kevin, be quiet.</p>

<p style="text-align: right;">Page 230</p> <p>1 W. VIGILANTE</p> <p>2 MR. HAVERTY: No. Excuse me, Dave.</p> <p>3 Q. Mr. Vigilante --</p> <p>4 MR. HAVERTY: No, no, this is --</p> <p>5 this is -- this is the third time that you</p> <p>6 not allowed -- you asked a question. He's</p> <p>7 giving you an answer. I'm sorry that you</p> <p>8 don't like the answer, but he's giving the</p> <p>9 answer and he's entitled to give the</p> <p>10 answer.</p> <p>11 MR. SCHULTZ: Kevin.</p> <p>12 MR. HAVERTY: Dave.</p> <p>13 MR. SCHULTZ: Kevin --</p> <p>14 MR. HAVERTY: Dave.</p> <p>15 MR. SCHULTZ: -- may I -- let me</p> <p>16 know when I may speak. Are you done?</p> <p>17 MR. HAVERTY: Yeah, I'm done.</p> <p>18 MR. SCHULTZ: Okay.</p> <p>19 MR. HAVERTY: Speak.</p> <p>20 MR. SCHULTZ: Here's my problem:</p> <p>21 Okay? He apparently doesn't ans -- doesn't</p> <p>22 understand the question I'm asking and I</p> <p>23 want to focus his attention on what I'm</p> <p>24 trying to get him to answer. Hold on. I</p> <p>25 was quiet while you interrupted. And so</p>	<p style="text-align: right;">Page 231</p> <p>1 W. VIGILANTE</p> <p>2 when he gets off on a tangent, I'd like to</p> <p>3 redirect him. That's perfectly appropriate</p> <p>4 and you -- I have wasted incredible amounts</p> <p>5 of time with this witness going off making</p> <p>6 speeches, being non-responsive and I'm</p> <p>7 simply trying to be efficient in this</p> <p>8 deposition.</p> <p>9 MR. HAVERTY: I'm sorry that you --</p> <p>10 MR. SCHULTZ: I'm already not going</p> <p>11 to finish today because of his --</p> <p>12 MR. HAVERTY: Well, he's not coming</p> <p>13 back, Dave, so you're finishing it. You're</p> <p>14 either finishing --</p> <p>15 MR. SCHULTZ: I have -- no, no.</p> <p>16 MR. HAVERTY: He's not coming back.</p> <p>17 MR. SCHULTZ: Kevin, I did not</p> <p>18 choose ten o'clock. You insisted on ten</p> <p>19 o'clock. I have a plane I cannot miss. It</p> <p>20 is not my problem and I am --</p> <p>21 MR. HAVERTY: Dave --</p> <p>22 MR. SCHULTZ: -- entitled to seven</p> <p>23 hours.</p> <p>24 MR. HAVERTY: You're going to -- and</p> <p>25 you're -- Dave, here's the story: This is</p>
<p style="text-align: right;">Page 232</p> <p>1 W. VIGILANTE</p> <p>2 the end of the line. You've gotten every</p> <p>3 benefit from this judge and I've had to</p> <p>4 give everything to you throughout this</p> <p>5 case.</p> <p>6 MR. SCHULTZ: Oh, Kevin.</p> <p>7 MR. HAVERTY: And I'm done.</p> <p>8 MR. SCHULTZ: Please.</p> <p>9 MR. HAVERTY: I am done. I'm done.</p> <p>10 Today is the end of this routine.</p> <p>11 MR. SCHULTZ: We'll find --</p> <p>12 MR. HAVERTY: Today --</p> <p>13 MR. SCHULTZ: What routine, Kevin?</p> <p>14 MR. HAVERTY: The fact that you've</p> <p>15 been on the offense the entire time for the</p> <p>16 last year and a half and --</p> <p>17 MR. SCHULTZ: The fact that you</p> <p>18 have a witness who can never start a</p> <p>19 deposition --</p> <p>20 MR. HAVERTY: And --</p> <p>21 MR. SCHULTZ: -- before 10:00 in the</p> <p>22 morning --</p> <p>23 MR. HAVERTY: And by the way --</p> <p>24 MR. SCHULTZ: -- and then has to</p> <p>25 catch a plane.</p>	<p style="text-align: right;">Page 233</p> <p>1 W. VIGILANTE</p> <p>2 MR. HAVERTY: And, by the way, you</p> <p>3 know, the way Medtronic has behaved</p> <p>4 throughout this litigation has been</p> <p>5 despicable, absolutely despicable.</p> <p>6 MR. SCHULTZ: That's it.</p> <p>7 MR. HAVERTY: Yeah, so we're</p> <p>8 finishing today or -- or he's not coming</p> <p>9 back. He's not coming back. End of story.</p> <p>10 MR. SCHULTZ: What has Medtronic</p> <p>11 done that's despicable, Kevin?</p> <p>12 MR. HAVERTY: Let me pull out all</p> <p>13 the transcripts. How -- the two -- the two</p> <p>14 depositions of Rachel Dennert. Even the --</p> <p>15 even the videographer yesterday --</p> <p>16 MR. SCHULTZ: Which I wasn't at --</p> <p>17 MR. HAVERTY: -- said to me it was</p> <p>18 despicable.</p> <p>19 MR. SCHULTZ: -- right?</p> <p>20 MR. HAVERTY: No, I don't care if</p> <p>21 you weren't that. It was Medtronic's</p> <p>22 counsel, and I hope that you were brought</p> <p>23 in because of the way they behaved.</p> <p>24 MR. SCHULTZ: I am --</p> <p>25 MR. HAVERTY: So, you know, I'm</p>

<p style="text-align: right;">Page 234</p> <p>1 W. VIGILANTE</p> <p>2 done. We're going to finish this</p> <p>3 deposition today. He's not coming back.</p> <p>4 MR. SCHULTZ: Kevin.</p> <p>5 MR. HAVERTY: I'm not -- I'm not</p> <p>6 doing it. I'm not producing him.</p> <p>7 MR. SCHULTZ: Well, we'll see about</p> <p>8 that.</p> <p>9 MR. HAVERTY: And by the way,</p> <p>10 here -- I'm sorry to do this to you: Could</p> <p>11 you please -- can you get that question</p> <p>12 back, the question he originally asked --</p> <p>13 MR. SCHULTZ: No, no, no.</p> <p>14 MR. HAVERTY: -- so we can see that</p> <p>15 he's --</p> <p>16 MR. SCHULTZ: No, no, no.</p> <p>17 MR. HAVERTY: No?</p> <p>18 MR. SCHULTZ: We're moving on.</p> <p>19 Okay? It's my deposition, Kevin, not</p> <p>20 yours.</p> <p>21 BY MR. SCHULTZ:</p> <p>22 Q. Mr. Vigilante, okay, here's -- I'm</p> <p>23 trying to be efficient here. I want to hear</p> <p>24 your opinion, okay, but I need to understand</p> <p>25 the context for it. The context for I think</p>	<p style="text-align: right;">Page 235</p> <p>1 W. VIGILANTE</p> <p>2 where you're going with this is that one of</p> <p>3 the reasons Medtronic failed to identify</p> <p>4 hazards is because they didn't appreciate, in</p> <p>5 your opinion, that the reservoir-filling</p> <p>6 process required the user to do things that</p> <p>7 were uncomfortable or stressful or unnatural.</p> <p>8 Is that a fair summary?</p> <p>9 A. So as I was explaining, and I</p> <p>10 think I'm going to answer your second question</p> <p>11 if I get done with my first. But there's a</p> <p>12 couple things in the process that Medtronic is</p> <p>13 asking users to do that are unnatural and that</p> <p>14 results in stressful postures. So the first</p> <p>15 thing --</p> <p>16 Q. And, therefore, they'll do it</p> <p>17 differently?</p> <p>18 A. Therefore, it's unnatural; and if</p> <p>19 it's unnatural, they're not going to naturally</p> <p>20 do it. And part of usability is having people</p> <p>21 to do things that are natural so that they</p> <p>22 don't need instructions and warnings to tell</p> <p>23 them to do something that's contrary to what</p> <p>24 they would believe is natural.</p> <p>25 Q. Are you about to --</p>
<p style="text-align: right;">Page 236</p> <p>1 W. VIGILANTE</p> <p>2 A. That's the -- that's the on --</p> <p>3 Q. -- show me what's unnatural?</p> <p>4 A. -- that's the whole point. I'm</p> <p>5 about to show you, so --</p> <p>6 Q. Then let me -- let me give you</p> <p>7 something that will help you.</p> <p>8 A. I don't need that. I don't need</p> <p>9 that. So --</p> <p>10 Q. I -- I would like you to use it --</p> <p>11 A. Let's stop.</p> <p>12 Q. -- please.</p> <p>13 A. Let me finish and then we can get</p> <p>14 on to your -- on to your -- your</p> <p>15 demonstration.</p> <p>16 Q. No, actually, I -- I'm the one</p> <p>17 that gets to ask the questions, Mr. Vigilante.</p> <p>18 MR. HAVERTY: Yeah, but you don't</p> <p>19 get to dictate his demonstration, Dave.</p> <p>20 MR. SCHULTZ: I didn't --</p> <p>21 MR. HAVERTY: He's answering your</p> <p>22 question. You're refusing --</p> <p>23 MR. SCHULTZ: Yes, I actually do,</p> <p>24 Kevin.</p> <p>25 MR. HAVERTY: No, you don't.</p>	<p style="text-align: right;">Page 237</p> <p>1 W. VIGILANTE</p> <p>2 Q. I'd like you to demonstrate the</p> <p>3 reservoir-filling process but use the vial of</p> <p>4 insulin because that is part of the process,</p> <p>5 is it not?</p> <p>6 A. I don't need a --</p> <p>7 Q. Here you go.</p> <p>8 A. I don't need it for what I was</p> <p>9 trying to answer for your initial question.</p> <p>10 So if I'm able to do that and if I need it for</p> <p>11 an additional question, I'll take that under</p> <p>12 advisement.</p> <p>13 But the point I was trying to make</p> <p>14 is that you've got the reservoir you're going</p> <p>15 to flip, so flipping it up, now I've got to</p> <p>16 elevate my shoulder, if you see where my right</p> <p>17 shoulder is, so before my right shoulder was</p> <p>18 down.</p> <p>19 THE VIDEOGRAPHER: Can you put your</p> <p>20 screen down, please. It's blocking.</p> <p>21 A. So as I'm filling it, tapping it,</p> <p>22 doing everything I need to do, my shoulders</p> <p>23 in a -- are in a -- a neutral posture. To</p> <p>24 remove the reservoir, I've got to flip it up</p> <p>25 putting my shoulder into a non-neutral</p>

<p style="text-align: right;">Page 238</p> <p>1 W. VIGILANTE</p> <p>2 posture. Now, I've got to rotate my wrist</p> <p>3 down and supinate it to turn and then -- I</p> <p>4 pulled it the wrong way -- and then pull.</p> <p>5 The more natural way to do it --</p> <p>6 the other thing I want to note too is that now</p> <p>7 I'm manipulating with my strong hand 'cause</p> <p>8 I'm right-handed, as you would expect, and</p> <p>9 I've got my dominant hand over my weak hand.</p> <p>10 Most things that require fine motor skills,</p> <p>11 for example, maybe turning a knob, a doorknob</p> <p>12 is a good example, if it's -- if you need some</p> <p>13 pressure on it, typically what you're doing is</p> <p>14 you're putting your strong hand under your</p> <p>15 weak hand. Very rarely does a user come up to</p> <p>16 a door and reverse it to turn the doorknob.</p> <p>17 So typically you've got your strong hand under</p> <p>18 your weak hand.</p> <p>19 Medtronic is asking them to switch</p> <p>20 that. They're asking them to go from a</p> <p>21 neutral position with your shoulders to a</p> <p>22 non-neutral position with your shoulders.</p> <p>23 They're asking you to make two different</p> <p>24 movements with your wrist. You've got to flex</p> <p>25 it down and you have to supinate it. If</p>	<p style="text-align: right;">Page 239</p> <p>1 W. VIGILANTE</p> <p>2 you're in a neutral position, you just have to</p> <p>3 supinate it. There is no flexion, so it's</p> <p>4 less stressful. And it's not consistent with</p> <p>5 conventional norms and it puts you in a less</p> <p>6 comfortable posture.</p> <p>7 So, again, looking at the task</p> <p>8 analysis, these things -- if they were done on</p> <p>9 the IFU that was provided to Mrs. Dennert,</p> <p>10 would have been a -- would have been and</p> <p>11 should have been identified.</p> <p>12 Q. What do you mean "not on the IFU</p> <p>13 provided"? What -- what are you saying there?</p> <p>14 I don't follow.</p> <p>15 A. Because the IFU provided to</p> <p>16 Ms. Dennert is different than the IFU they did</p> <p>17 the task analysis on, they did the usability</p> <p>18 test on. That was something --</p> <p>19 Q. In what way?</p> <p>20 A. -- that I argued that --</p> <p>21 There's several ways. One, in the</p> <p>22 IFU they have the insulin bottle, and if this</p> <p>23 is our table, sitting on the table for the --</p> <p>24 whoops -- insertion, the pumping, and the</p> <p>25 filling. I -- I don't have that locked in.</p>
<p style="text-align: right;">Page 240</p> <p>1 W. VIGILANTE</p> <p>2 So in the IFU they did the task</p> <p>3 analysis on, usability testing on they have</p> <p>4 the insulin bottle on the table and they're</p> <p>5 removing the reservoir from the insulin vial</p> <p>6 while it's still sitting on the table.</p> <p>7 In the IFU that is in this packet</p> <p>8 that was given to Mrs. Dennert, that's not</p> <p>9 what they do. They show the user -- I don't</p> <p>10 know if you can zoom in on that, these top</p> <p>11 steps. They show the user removing,</p> <p>12 pressurizing with the -- the reservoir upside</p> <p>13 down and then turning it upside down to push</p> <p>14 air in and pull out in Step Number 3. Turning</p> <p>15 it upside down to push air in and pull air out</p> <p>16 and then to tap the bottles in Step 4. In</p> <p>17 Step 5 -- I'm sorry. 3 is to pump the air</p> <p>18 into the insulin reservoir. 4 is to pull the</p> <p>19 insulin into the reservoir from the vial.</p> <p>20 Step 5 is to tap the bubbles out. Step 5 is</p> <p>21 continuation of stepping -- tapping the</p> <p>22 bubbles out and getting the insulin to the</p> <p>23 level you want it, and then 6 is removing the</p> <p>24 reservoir. And 6 you have to go from this to</p> <p>25 this (indicating); and that's where the</p>	<p style="text-align: right;">Page 241</p> <p>1 W. VIGILANTE</p> <p>2 problem is because if you go like this</p> <p>3 (indicating) and you remove -- I'm sorry.</p> <p>4 You're going -- you're supposed to go like</p> <p>5 this to this (indicating) and remove the</p> <p>6 reservoir. But what's happening is</p> <p>7 Ms. Dennert in the YouTube videos I saw -- I</p> <p>8 saw and Mark Curtis in his demonstration, they</p> <p>9 don't do it like that. They're filling the</p> <p>10 tube. They're tapping it out. They're</p> <p>11 getting to the right level and they're</p> <p>12 removing it. And when you do that, you're</p> <p>13 giving the insulin in the vial opportunity to</p> <p>14 spill out on to the top of your reservoir.</p> <p>15 Now, with the top of reservoir</p> <p>16 contaminated, the next step is to put it into</p> <p>17 your P-cap and now you've just contaminated</p> <p>18 your vents. Take out your plunger, put it in</p> <p>19 the pump, and next thing you know, you're</p> <p>20 getting insulin out of the cannula quick --</p> <p>21 quick disconnect. You think your priming is</p> <p>22 done. You go about your business.</p> <p>23 Unbeknownst to you the plunger continues to --</p> <p>24 to move in delivering unwanted insulin.</p> <p>25 Q. Done?</p>

<p style="text-align: right;">Page 242</p> <p>1 W. VIGILANTE</p> <p>2 A. Yes.</p> <p>3 Q. So as I understand it, you're</p> <p>4 saying that the process or the requirement</p> <p>5 that you flip the vial over is unnatural and</p> <p>6 requires a stressful and uncomfortable</p> <p>7 position; correct?</p> <p>8 A. Yeah, having to remove the --</p> <p>9 Q. May I see it?</p> <p>10 A. Sure. Having to remove the</p> <p>11 reservoir from over the insulin means you have</p> <p>12 to swap it.</p> <p>13 Q. Okay. Mr. Vigilante, do you see</p> <p>14 that I have the reservoir underneath right</p> <p>15 now?</p> <p>16 A. Sure.</p> <p>17 Q. You see that I now have it on top?</p> <p>18 A. Yep.</p> <p>19 Q. You see that I've flipped it back</p> <p>20 to being underneath?</p> <p>21 A. Yes.</p> <p>22 Q. You see that I've never moved my</p> <p>23 shoulder during that process?</p> <p>24 A. You still haven't tried to take it</p> <p>25 off.</p>	<p style="text-align: right;">Page 243</p> <p>1 W. VIGILANTE</p> <p>2 Q. I -- just one at a time, please.</p> <p>3 A. Sure.</p> <p>4 Q. Did you see that I did not move my</p> <p>5 shoulder?</p> <p>6 A. I did see that.</p> <p>7 Q. Okay.</p> <p>8 A. And are --</p> <p>9 Q. If I place it on the table --</p> <p>10 A. -- are you right-handed or</p> <p>11 left-handed? Can we put that on the record?</p> <p>12 Q. Sure. I'm right-handed. I've</p> <p>13 been using --</p> <p>14 A. Okay.</p> <p>15 Q. -- my left hand, but I can do it</p> <p>16 with my right hand as well.</p> <p>17 A. Okay.</p> <p>18 Q. Okay. Do you know, by the way,</p> <p>19 which -- what the neurological studies of</p> <p>20 Rachel Dennert have shown as to the dominance</p> <p>21 of her hand?</p> <p>22 A. Nope.</p> <p>23 Q. Okay.</p> <p>24 A. Doesn't matter.</p> <p>25 Q. Do you know if --</p>
<p style="text-align: right;">Page 244</p> <p>1 W. VIGILANTE</p> <p>2 A. It's weak hand, strong hand.</p> <p>3 Q. Do you know which hand is her</p> <p>4 dominant hand?</p> <p>5 A. It doesn't matter. It's weak</p> <p>6 hand, strong hand.</p> <p>7 Q. So your point is that people can't</p> <p>8 or don't use their weak hand for any part of a</p> <p>9 process like this?</p> <p>10 A. I'm not saying they don't. What</p> <p>11 I'm saying is that the process that is in that</p> <p>12 IFU is unnatural, and when you don't point it</p> <p>13 out in the IFU, you're going to have people</p> <p>14 doing it wrong and that is foreseeable --</p> <p>15 Q. That's the --</p> <p>16 A. -- and the consequence of that</p> <p>17 foreseeability is getting insulin on the top</p> <p>18 of that --</p> <p>19 Q. But the --</p> <p>20 A. -- reservoir.</p> <p>21 Q. -- the part that I don't</p> <p>22 understand, which is all I'm trying to find</p> <p>23 out from you, is what's unnatural? What makes</p> <p>24 this unnatural?</p> <p>25 A. Well, continue. I'll tell you.</p>	<p style="text-align: right;">Page 245</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay. I've got the reservoir.</p> <p>3 Put it on the table and remove it.</p> <p>4 A. There's no -- there's no</p> <p>5 requirement to put it on the table.</p> <p>6 Q. Okay. It's off the table. What's</p> <p>7 unnatural about that?</p> <p>8 A. Two things. You have your weak</p> <p>9 hand under your strong hand. That is a</p> <p>10 unnatural position.</p> <p>11 Q. Okay. Right now will you agree</p> <p>12 with me --</p> <p>13 MR. SCHULTZ: Do you have this on</p> <p>14 the video?</p> <p>15 Q. Do you agree with me that I have</p> <p>16 my strong hand, my dominant hand --</p> <p>17 A. Yes.</p> <p>18 Q. -- on the reservoir --</p> <p>19 A. Yes.</p> <p>20 Q. -- underneath, right?</p> <p>21 The vial is not --</p> <p>22 A. Yes.</p> <p>23 Q. -- on the table and I've just</p> <p>24 removed the insulin reservoir from the vial?</p> <p>25 A. You did, and you could do that,</p>

<p style="text-align: right;">Page 246</p> <p>1 W. VIGILANTE</p> <p>2 but the problem is the step before. You're</p> <p>3 holding the unit with your strong hand.</p> <p>4 Q. Okay. You want me to do it with</p> <p>5 my weak hand? Now I'm holding it with my weak</p> <p>6 hand.</p> <p>7 A. No, you're not --</p> <p>8 Q. How is that unnatural?</p> <p>9 A. -- you're not -- you're not</p> <p>10 understanding.</p> <p>11 Q. I -- I most clearly am not</p> <p>12 understanding.</p> <p>13 A. No, you're not, so let me --</p> <p>14 Q. So --</p> <p>15 A. -- show you.</p> <p>16 Q. No. Why don't you walk me through</p> <p>17 it? I'll hold it. You tell me what I need to</p> <p>18 do.</p> <p>19 A. Well, you need to get it off the</p> <p>20 table.</p> <p>21 Q. Okay. Which hand do you want --</p> <p>22 A. You need to --</p> <p>23 Q. -- me to hold it in?</p> <p>24 A. The strong hand's fine.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 247</p> <p>1 W. VIGILANTE</p> <p>2 A. We'll do it by the -- we'll do it</p> <p>3 by the instructions.</p> <p>4 Q. Okay.</p> <p>5 A. All right. So we've got our --</p> <p>6 you can hold the reservoir with your strong</p> <p>7 hand. The other way. The other way. There</p> <p>8 you go. Now, you're going to be pumping air</p> <p>9 into the insulin vial.</p> <p>10 Q. Okay.</p> <p>11 A. Okay. You got it on there. Now,</p> <p>12 you're going to --</p> <p>13 Q. It's on there.</p> <p>14 A. -- you're going to turn the unit</p> <p>15 over.</p> <p>16 Q. Okay.</p> <p>17 A. You're going to bring it up</p> <p>18 because you're looking for air bubbles.</p> <p>19 Q. Bring what up?</p> <p>20 A. You're not looking at it down,</p> <p>21 you're bringing the unit up.</p> <p>22 Okay. Hold on a minute. You're</p> <p>23 going to pump air in and out. Using your</p> <p>24 right hand you're going to push the plunger</p> <p>25 in.</p>
<p style="text-align: right;">Page 248</p> <p>1 W. VIGILANTE</p> <p>2 Q. Okay.</p> <p>3 A. Using your weak hand you're going</p> <p>4 to grab the reservoir.</p> <p>5 Q. Okay.</p> <p>6 A. I'm sorry. The transfer guard.</p> <p>7 Q. Okay.</p> <p>8 A. And you're going to pull the</p> <p>9 plunger out.</p> <p>10 No, no.</p> <p>11 Q. Oh, the plunger. I'm sorry.</p> <p>12 Okay.</p> <p>13 A. Okay. Now, you're going to hold</p> <p>14 the plunger body with your left hand.</p> <p>15 Q. Okay.</p> <p>16 A. Okay. Now, you're going to flick</p> <p>17 with your right hand.</p> <p>18 Now, you're going to hold your</p> <p>19 left -- you're going to hold the transfer</p> <p>20 guard with your left hand and you're going to</p> <p>21 take your right hand and you're going to move</p> <p>22 the plunger in to your -- you got to be able</p> <p>23 to see where it's going. You got good eyes</p> <p>24 that can see those marks at that distance?</p> <p>25 Q. Yeah.</p>	<p style="text-align: right;">Page 249</p> <p>1 W. VIGILANTE</p> <p>2 A. Yeah. Well, I think most people</p> <p>3 are going to hold it up here where they can</p> <p>4 see it which becomes part of the problem. The</p> <p>5 next step is, is you're going to flip it over.</p> <p>6 Q. Which hand do you want me to use?</p> <p>7 A. It shows that you're going to flip</p> <p>8 it over with your right hand on the reservoir.</p> <p>9 You just did it wrong.</p> <p>10 Q. On the reservoir.</p> <p>11 Oh.</p> <p>12 A. You just did it wrong.</p> <p>13 Q. Does it matter if I --</p> <p>14 A. It does matter because you're</p> <p>15 asking people to follow your IFU and then</p> <p>16 giving them a hard time if they don't, and I'm</p> <p>17 telling you the IFU is poorly done --</p> <p>18 Q. Does it matter if --</p> <p>19 A. -- so you just messed it up.</p> <p>20 Q. -- when I flip -- really? And --</p> <p>21 A. Yes.</p> <p>22 Q. -- and that's -- that's what's</p> <p>23 causing the temporary blocked vent, is that</p> <p>24 instead of grabbing it with the reservoir and</p> <p>25 flipping it, I -- I used the vial and flipped</p>

<p style="text-align: right;">Page 250</p> <p>1 W. VIGILANTE</p> <p>2 it?</p> <p>3 A. What's causing it is two things.</p> <p>4 One is that the IFU is not clear, does not</p> <p>5 give warning; and two, the IFU is asking you</p> <p>6 to do tasks and swap hands unnecessarily. So</p> <p>7 if you bring it down to a more natural, more</p> <p>8 efficient manner of doing it, you wouldn't be</p> <p>9 in the position to make these types of</p> <p>10 mistakes.</p> <p>11 Q. Well, what's it --</p> <p>12 A. How many times did you switch</p> <p>13 hands? It's going to be --</p> <p>14 Q. As many --</p> <p>15 A. -- on the video.</p> <p>16 Q. -- times as you asked me to.</p> <p>17 A. I didn't ask you to. The IFU</p> <p>18 asked you to.</p> <p>19 Q. The IFU just shows that somebody's</p> <p>20 holding it.</p> <p>21 A. The IFU's telling you --</p> <p>22 Q. Does it matter if I switch my</p> <p>23 hand?</p> <p>24 A. If you're following the IFU, you</p> <p>25 are.</p>	<p style="text-align: right;">Page 251</p> <p>1 W. VIGILANTE</p> <p>2 Q. If -- but if -- if I find that</p> <p>3 unnatural for some reason, does the fact that</p> <p>4 I use one hand or the other hand make a</p> <p>5 difference? It doesn't, does it? Not in</p> <p>6 terms of --</p> <p>7 A. It shouldn't -- it -- I'm sorry.</p> <p>8 It shouldn't make a difference. It shouldn't</p> <p>9 make a difference.</p> <p>10 Q. It doesn't make a difference --</p> <p>11 A. So taking the --</p> <p>12 Q. -- in terms --</p> <p>13 A. -- taking the insulin vial off,</p> <p>14 either for inverted or upside down shouldn't</p> <p>15 make a difference to the user, it shouldn't,</p> <p>16 but it does. It makes a big difference. It</p> <p>17 makes a deadly difference and that's the</p> <p>18 problem. So it shouldn't make a difference to</p> <p>19 the user because you're right, ten users come</p> <p>20 in, eight, nine of them may do it one way, one</p> <p>21 or two of them may not.</p> <p>22 Q. Yeah, does it...</p> <p>23 (Pause.)</p> <p>24 Q. Where does it say in the IFU that</p> <p>25 you have to hold the vial and the reservoir in</p>
<p style="text-align: right;">Page 252</p> <p>1 W. VIGILANTE</p> <p>2 the hand that's depicted?</p> <p>3 A. There's nothing in the IFU that</p> <p>4 says you don't have to do that. So, again, it</p> <p>5 gets back to if you're going to provide</p> <p>6 somebody with a process and you want them to</p> <p>7 do it a certain way to prevent a very, very,</p> <p>8 very severe hazard, you have to tell them, you</p> <p>9 have to give them explicit instructions, you</p> <p>10 got to give them explicit warnings. If it's</p> <p>11 okay to use it any which way you want, you</p> <p>12 have to recognize that as a designer and make</p> <p>13 sure that a minor change in the process that's</p> <p>14 depicted doesn't result in somebody becoming</p> <p>15 comatose and nearly dying. That -- that's</p> <p>16 the -- that's the point.</p> <p>17 Q. In terms of the temporary blocked</p> <p>18 vent condition, what matters is that the</p> <p>19 patient follow the instruction that the</p> <p>20 reservoir is to be above the vial when the</p> <p>21 reservoir is removed from the transfer guard;</p> <p>22 right? That's what --</p> <p>23 MR. HAVERTY: What -- what in --</p> <p>24 Q. -- matters ultimately; right?</p> <p>25 MR. HAVERTY: What instruction?</p>	<p style="text-align: right;">Page 253</p> <p>1 W. VIGILANTE</p> <p>2 A. Yeah, so ultimately the way that</p> <p>3 the unit's set up to avoid the anomaly with</p> <p>4 the prime/fill anomaly due to the blocked</p> <p>5 vents is to remove the reservoir when it's on</p> <p>6 top of the insulin vial. And you've already</p> <p>7 made my point several times, that it doesn't</p> <p>8 matter. It shouldn't matter which hand you do</p> <p>9 it in. It shouldn't matter to the user</p> <p>10 because if they -- if they make a mistake, if</p> <p>11 they do it in a way that's not depicted in the</p> <p>12 IFU, it shouldn't result in a catastrophic</p> <p>13 injury; and because it can result in a</p> <p>14 catastrophic injury, the least you could have</p> <p>15 done was made sure that the IFU was explicit</p> <p>16 and specific and provided warning and provided</p> <p>17 information to the user that this is important</p> <p>18 you do it this way. It's important because if</p> <p>19 you don't, you can have a problem; and if you</p> <p>20 have a problem, it can cause severe and</p> <p>21 permanent injury.</p> <p>22 Q. What you're calling the</p> <p>23 catastrophic injury is not caused by what hand</p> <p>24 the patient chooses to hold anything in. It's</p> <p>25 caused by removing the reservoir from the</p>

<p style="text-align: right;">Page 254</p> <p>1 W. VIGILANTE</p> <p>2 transfer guard with the vial above. Would you</p> <p>3 agree with that?</p> <p>4 A. It -- they're related.</p> <p>5 Q. It doesn't matter which hand I'm</p> <p>6 holding it in. The issue, if it -- if it's</p> <p>7 going to exist at all, exists by virtue of the</p> <p>8 orientation of the vial above the reservoir;</p> <p>9 right?</p> <p>10 A. It -- it does, but they're</p> <p>11 related, and they're related because the</p> <p>12 orientation of the vial and the reservoir is a</p> <p>13 function of the different steps you're doing;</p> <p>14 and you're starting off holding it with the</p> <p>15 insulin vial -- you're starting off with the</p> <p>16 insulin vial down. You're flipping it up in a</p> <p>17 natural position so that you can get the</p> <p>18 bubbles out so that you can see and then</p> <p>19 you're telling the user to flip it back over</p> <p>20 to avoid a catastrophic injury, but you don't</p> <p>21 highlight it, you don't put any notation in</p> <p>22 here, you don't put any text in here to</p> <p>23 describe what you just did and why you just</p> <p>24 did it.</p> <p>25 (Pause.)</p>	<p style="text-align: right;">Page 255</p> <p>1 W. VIGILANTE</p> <p>2 Q. People who use these devices, some</p> <p>3 are left-handed, some are right-handed --</p> <p>4 A. Sure.</p> <p>5 Q. -- correct?</p> <p>6 Are you saying that the IFUs</p> <p>7 should be created one for left-handed people</p> <p>8 and one for right-handed people?</p> <p>9 A. I don't think so. I think the IFU</p> <p>10 should be clear if they're requiring you to do</p> <p>11 it exactly the way it is, which to avoid this</p> <p>12 hazard you have to do it exactly the way it</p> <p>13 is, then they should tell you.</p> <p>14 Q. Well, is it your opinion that --</p> <p>15 A. All right. If they -- if they're</p> <p>16 giving you the ability to swap strong hand for</p> <p>17 weak hand, then, yeah, that's fine as well.</p> <p>18 Q. Is it your testimony,</p> <p>19 Mr. Vigilante, that the user has to do -- I</p> <p>20 think the phrase you just used was everything</p> <p>21 exactly as it is in the F -- IFU in order to</p> <p>22 avoid a temporary blocked vent?</p> <p>23 MR. HAVERTY: Objection. That's not</p> <p>24 what he testified.</p> <p>25 MR. SCHULTZ: Well, that's what I'm</p>
<p style="text-align: right;">Page 256</p> <p>1 W. VIGILANTE</p> <p>2 trying to find out 'cause that's what I</p> <p>3 thought he said.</p> <p>4 A. It's my understanding that</p> <p>5 Medtronic and Unomedical provided this --</p> <p>6 Q. That was --</p> <p>7 A. -- or maybe Medtronic provided</p> <p>8 this --</p> <p>9 Q. Can you answer my question?</p> <p>10 A. I'm not done.</p> <p>11 -- provided this IFU --</p> <p>12 Q. I know you're not done. I'm just</p> <p>13 wondering if you can answer my question.</p> <p>14 A. -- to -- to instruct the user on</p> <p>15 how to do it properly and safely. So if you</p> <p>16 don't follow the IFU, you're not doing it</p> <p>17 properly and you're not doing it safely. The</p> <p>18 question is: Does the user realize that</p> <p>19 they're not doing it properly and, therefore,</p> <p>20 it's unsafe? And the answer is no because</p> <p>21 there's no warning in here to tell you that.</p> <p>22 So what happens, and we've seen it with Rachel</p> <p>23 Dennert, we've seen it with Mark Curtis, we've</p> <p>24 seen it with the YouTube videos that I found,</p> <p>25 that Medtronic's own people found, that people</p>	<p style="text-align: right;">Page 257</p> <p>1 W. VIGILANTE</p> <p>2 are not doing it properly and that exposes</p> <p>3 them to the potential hazard.</p> <p>4 Q. In point of fact, we haven't seen</p> <p>5 it with Rachel Dennert. There's no testimony</p> <p>6 and no evidence in this case that anyone saw</p> <p>7 her remove the reservoir from the vial with</p> <p>8 the vial above; correct?</p> <p>9 A. That's correct.</p> <p>10 Q. Okay.</p> <p>11 A. The testimony from Mrs. Dennert's</p> <p>12 mother is that she did it correctly.</p> <p>13 Q. Correct.</p> <p>14 A. But somehow or another the vent</p> <p>15 got blocked.</p> <p>16 Q. Well, Mrs. Dennert did not testify</p> <p>17 that the vent got blocked. She doesn't know,</p> <p>18 does she?</p> <p>19 A. I didn't say that.</p> <p>20 Q. Okay.</p> <p>21 A. But we do know that Rachel had</p> <p>22 testified -- or stated to her mother that</p> <p>23 earlier she got -- she thought she got some</p> <p>24 insulin on the reservoir while doing the</p> <p>25 change. So, again --</p>

<p style="text-align: right;">Page 258</p> <p>1 W. VIGILANTE</p> <p>2 Q. Did she say she got it on the</p> <p>3 reservoir or did she say she got it on the</p> <p>4 night table and the end of the infusion set?</p> <p>5 A. Maybe it's the latter.</p> <p>6 Q. Yeah.</p> <p>7 A. Sorry.</p> <p>8 Q. And that's not the infusion set</p> <p>9 that's at issue in this case in any event, is</p> <p>10 it?</p> <p>11 A. My understanding is that they were</p> <p>12 both swapped out at the ten, eleven o'clock</p> <p>13 changing.</p> <p>14 Q. Now, but the insulin spillage for</p> <p>15 which we don't have any information as to how</p> <p>16 it occurred occurred at six o'clock or 6:46;</p> <p>17 right?</p> <p>18 A. The insulin spillage that Rachel</p> <p>19 reported to her mother was at 6:00 -- the</p> <p>20 6:30 --</p> <p>21 Q. Right.</p> <p>22 A. -- let's say the 6:30 change.</p> <p>23 Q. So back to my question. In order</p> <p>24 to avoid the temporary blocked vent condition,</p> <p>25 the thing that is necessary is that the</p>	<p style="text-align: right;">Page 259</p> <p>1 W. VIGILANTE</p> <p>2 reservoir be removed from the vial, right,</p> <p>3 with the vial below the reservoir; correct?</p> <p>4 Isn't that a true statement?</p> <p>5 A. The true statement is, is to avoid</p> <p>6 it is --</p> <p>7 Q. No --</p> <p>8 A. -- to follow what the IFU --</p> <p>9 Q. -- you know what, Mr. Vigilante,</p> <p>10 that's a simple question. It's a yes-or-no</p> <p>11 question and I would appreciate a yes or a no</p> <p>12 answer.</p> <p>13 Isn't it true that to avoid the</p> <p>14 temporary blocked vent condition the step that</p> <p>15 is required is that the reservoir be removed</p> <p>16 from the transfer guard with the vial in the</p> <p>17 down position? Is that true?</p> <p>18 A. That is not true.</p> <p>19 Q. Okay. Do you -- would you agree</p> <p>20 with me that Step 7 in the IFU depicts the</p> <p>21 vial at the time of removal of the reservoir</p> <p>22 from the transfer guard as beneath, below the</p> <p>23 reservoir which --</p> <p>24 A. No.</p> <p>25 Q. It doesn't depict that?</p>
<p style="text-align: right;">Page 260</p> <p>1 W. VIGILANTE</p> <p>2 A. Not in this IFU.</p> <p>3 Q. Okay. Well, why don't we mark --</p> <p>4 I don't know what IFU you're looking at. Why</p> <p>5 don't we mark the one that Ms. Dennert had.</p> <p>6 MR. HAVERTY: Dave, just for the</p> <p>7 record, this is the one that Ms. Dennert</p> <p>8 had, in fact, because it came from her</p> <p>9 supplies.</p> <p>10 A. Are you marking that?</p> <p>11 Q. Yes, I am.</p> <p>12 (Exhibit Vigilante-15, two-page</p> <p>13 document entitled Medtronic MiniMed</p> <p>14 Paradigm Reservoir Rx Only, is marked for</p> <p>15 identification.)</p> <p>16 Q. Now, Mr. Vigilante, I'm handing</p> <p>17 you what's been marked as Exhibit 15 which is</p> <p>18 a true and correct copy of an IFU that was in</p> <p>19 use at the time that Rachel Dennert had her</p> <p>20 reservoir.</p> <p>21 MR. HAVERTY: Are you making</p> <p>22 representation that it is the same IFU as</p> <p>23 she would have been produced?</p> <p>24 MR. SCHULTZ: Yeah.</p> <p>25 MR. HAVERTY: Okay. Well, let's --</p>	<p style="text-align: right;">Page 261</p> <p>1 W. VIGILANTE</p> <p>2 just for the record, let's note that this</p> <p>3 IFR [sic] that Mr. Vigilante is using is</p> <p>4 from a reservoir box that was provided to</p> <p>5 Ms. Dennert back in July of 2009 with</p> <p>6 Reference Number MMT-326A, Lot Number</p> <p>7 H7480331, and I guess that the serial</p> <p>8 number is 2012/05 in case there are any</p> <p>9 discrepancies between one that --</p> <p>10 Q. Step 6 in both Exhibit 15 and the</p> <p>11 IFU that you have been using depict the</p> <p>12 removal of the reservoir from the transfer</p> <p>13 guard; true?</p> <p>14 A. They do, but that wasn't your</p> <p>15 question.</p> <p>16 Q. Do they both depict at the time of</p> <p>17 removal of the reservoir from the transfer</p> <p>18 guard that the vial is below the reservoir?</p> <p>19 A. They both do that in Step</p> <p>20 Number 6.</p> <p>21 Q. Okay. And -- and you can tell</p> <p>22 that by looking at these; right?</p> <p>23 A. Sure.</p> <p>24 Q. Okay. And it's -- there's nothing</p> <p>25 unnatural, is there, about removal of the</p>

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1 W. VIGILANTE
2 reservoir from the transfer guard with the
3 vial beneath the reservoir?
4 A. Yes, there is. I just explained
5 that before you --
6 Q. What --
7 A. -- took it off me and started
8 demonstrating your own demonstrating, arguably
9 demonstrating why it's a silly process and why
10 mistakes can be made and why they should have
11 figured this out.
12 Q. Why is it unnatural --
13 A. Here, give me --
14 Q. -- to remove -- let me finish my
15 question --
16 A. I'm sorry.
17 Q. -- please.
18 A. Yeah, you're right.
19 Q. Why is it unnatural to remove the
20 reservoir from the transfer guard with the
21 vial held beneath it?
22 A. May I see it?
23 Q. Can you tell me?
24 A. May I see it?
25 Q. Well, can -- just tell me if you

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1 W. VIGILANTE
2 it.
3 Now, a more natural position,
4 considering Step 5 -- you're in this position
5 again (indicating) -- a more natural position
6 is keeping your strong hand under your weak
7 hand, turning it, pulling it down. As you
8 will see, there's no reason to have my
9 shoulder up. My shoulder is in a neutral
10 position and there's no reason for me to flex
11 my wrist. That's a more natural position.
12 MR. SCHULTZ: Why don't you mark
13 this, please?
14 (Exhibit Vigilante-16, insulin vial,
15 is marked for identification.)
16 (Pause from the stenographic
17 record.)
18 MR. SCHULTZ: All right. Apparently
19 we have five minutes left on the tape, so
20 we need to take a break.
21 MR. HAVERTY: Yeah.
22 THE VIDEOGRAPHER: We are now going
23 off the video record. That concludes DVD
24 Number 3. The time is 15:36.
25 (A recess is held from 3:36 p.m. to

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1 W. VIGILANTE
2 can answer my question --
3 A. Well, first of all --
4 Q. -- as posed.
5 A. -- it is -- it is my reservoir and
6 transfer guard, so I -- I'm going to ask you
7 to give it back to me. If you want --
8 Q. Okay.
9 A. -- to keep your insulin vial --
10 Q. Here you go.
11 A. -- and -- that's fine.
12 Q. I'll get you my own reservoir and
13 transfer guard and then I'll ask you the
14 question.
15 A. So the -- the thing that counsel
16 is neglecting to state is that in -- in Step 5
17 the reservoir is on top and it's held in this
18 position. This is the last position in Step 5
19 that the user is in, like this (indicating).
20 Step 6 wants you to flip it like
21 this (indicating). So now we have our strong
22 hand above our weak hand. We have our
23 shoulder flexed. And now to remove the
24 reservoir. I've got to flex my wrist and I
25 got to turn it. Oop. Wrong way. And turn

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1 W. VIGILANTE
2 3:48 p.m.)
3 (The following is not recorded on
4 the video record.)
5 (Exhibit Vigilante-17, one-page
6 document entitled Medtronic MiniMed
7 Paradigm Reservoir Rx Only, is marked for
8 identification.)
9 MR. HAVERTY: We just had the IFU
10 from Rachel Dennert's supplies marked as
11 Vigilante-17 and that comes out of a
12 Paradigm Reservoir Reference Number
13 MMT-326A, Lot Number H7480331 and its date
14 of manufacture is 2012 -- or no. It can't
15 be. Must be the expiration date 2012/05.
16 (Time noted is 3:49 p.m.)
17
18
19
20
21 _____
22 William J. Vigilante, Jr., PhD, CPE
23 Subscribed and sworn to before me
24 this ____ day of _____, 2016.
25 _____
NOTARY PUBLIC

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<p>1 W. VIGILANTE</p> <p>2 I N D E X</p> <p>3 WITNESS PAGE</p> <p>4 William J. Vigilante, PhD, CPE</p> <p>5 BY MR. SCHULTZ 6</p> <p>6 E X H I B I T S</p> <p>7 NUMBER DESCRIPTION PAGE</p> <p>8 Exhibit Vigilante-1, multipage document 17</p> <p>9 entitled William J. Vigilante Jr., PhD,</p> <p>10 Exhibit Vigilante-2, multipage document 66</p> <p>11 entitled The Experts Robson Forensic, The</p> <p>12 Exhibit Vigilante-3, multipage document 67</p> <p>13 entitled The Experts Robson Forensic,</p> <p>14 Human Factors &</p> <p>15 Exhibit Vigilante-4, multipage document 67</p> <p>16 entitled The Experts Robson Forensic,</p> <p>17 Medical Device</p> <p>18 Exhibit Vigilante-5, multipage document 116</p> <p>19 entitled William Vigilante Human Factors</p> <p>20 ExpertVigilante Forensic</p> <p>21 Exhibit Vigilante-6, multipage document 119</p> <p>22 entitled Human Factors Expert Services</p> <p>23 Vigilante Forensic</p> <p>24 Exhibit Vigilante-7, multipage document 120</p> <p>25 entitled Bill Vigilante LinkedIn</p> <p>Exhibit Vigilante-8, multipage document 121</p> <p>entitled William J. Vigilante, PhD, CPE -</p> <p>SEAK, Inc. Expert Witness Directory</p> <p>Exhibit Vigilante-9, multipage document 127</p> <p>entitled William J. Vigilante, Jr.: Real</p> <p>Estate - Human Factors: JurisPro Expert</p> <p>Witness Directory</p>	<p>1 INDEX CONTINUED</p> <p>2 Exhibit Vigilante-10, Report of William 165</p> <p>3 J. Vigilante, Jr., PhD, CPE dated April</p> <p>4 19, 2016</p> <p>5 Exhibit Vigilante-11, letter dated June 165</p> <p>6 16, 2016 addressed to Kevin Haverty, Esq.</p> <p>7 Exhibit Vigilante-12, multipage document 217</p> <p>8 entitled Report of Protocol EP002 and</p> <p>9 EP003: Usability Study of the Platform 3</p> <p>10 User-Filled Reservoir Assembly and Its</p> <p>11 Instructions for Use</p> <p>12 Exhibit Vigilante-13, multipage document 217</p> <p>13 entitled ER-99-11-09-2256 Engineering</p> <p>14 Report</p> <p>15 Exhibit Vigilante-14, multipage document 218</p> <p>16 entitled ER-99-12-13-2285 Engineering</p> <p>17 Report</p> <p>18 Exhibit Vigilante-15, two-page document 260</p> <p>19 entitled Medtronic MiniMed Paradigm</p> <p>20 Reservoir Rx Only</p> <p>21 Exhibit Vigilante-16, insulin vial 264</p> <p>22 Exhibit Vigilante-17, one-page document 265</p> <p>23 entitled Medtronic MiniMed Paradigm</p> <p>24 Reservoir Rx Only</p> <p>25</p>
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<p>1 CERTIFICATE</p> <p>2 COMMONWEALTH OF PENNSYLVANIA)</p> <p>3) ss:</p> <p>4 COUNTY OF PHILADELPHIA)</p> <p>5 I, Debra Sapio Lyons, a Registered</p> <p>6 Diplomat Reporter, a Certified Realtime Reporter,</p> <p>7 a Certified Realtime Captioner, an Approved</p> <p>8 Reporter of the United States District Court for</p> <p>9 the Eastern District of Pennsylvania, a Certified</p> <p>10 Court Reporter for the State of New Jersey; and</p> <p>11 Notary Public within and for the States of New</p> <p>12 Jersey, New York and the Commonwealth of</p> <p>13 Pennsylvania do hereby certify:</p> <p>14 That William J. Vigilante, Jr., PhD,</p> <p>15 CPE, the witness whose deposition is hereinbefore</p> <p>16 set forth, was duly sworn by me and that such</p> <p>17 deposition is a true record of the testimony</p> <p>18 given by such witness, to the best of my ability</p> <p>19 and thereafter reduced to typewriting under my</p> <p>20 direction.</p> <p>21 I further certify that I am not related</p> <p>22 to any of the parties to this action by blood or</p> <p>23 marriage and that I am in no way interested in</p> <p>24 the outcome of the matter.</p> <p>25 In witness whereof, I have hereunto set</p> <p>my hand this 22nd day of August, 2016.</p> <p>DEBRA SAPIO LYONS</p> <p>CRR, RDR, CRC, CCR, CPE</p>	<p>1 NAME OF CASE:</p> <p>2 DATE OF DEPOSITION:</p> <p>3 NAME OF WITNESS:</p> <p>4 Reason Codes:</p> <p>5 1. To clarify the record.</p> <p>6 2. To conform to the facts.</p> <p>7 3. To correct transcription errors.</p> <p>8 Page _____ Line _____ Reason _____</p> <p>9 From _____ to _____</p> <p>10 Page _____ Line _____ Reason _____</p> <p>11 From _____ to _____</p> <p>12 Page _____ Line _____ Reason _____</p> <p>13 From _____ to _____</p> <p>14 Page _____ Line _____ Reason _____</p> <p>15 From _____ to _____</p> <p>16 Page _____ Line _____ Reason _____</p> <p>17 From _____ to _____</p> <p>18 Page _____ Line _____ Reason _____</p> <p>19 From _____ to _____</p> <p>20 Page _____ Line _____ Reason _____</p> <p>21 From _____ to _____</p> <p>22 Page _____ Line _____ Reason _____</p> <p>23 From _____ to _____</p> <p>24</p> <p>25</p>

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